

ENGLISH FOR WORK / PLATFORMS / ASSAYS / TRANSLATION / PARTNERING

Biotechnology English

Explain the signal. Define the claim. Connect evidence to decisions.



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Eight practical lessons. Eleven extended conversations.

Vocabulary, phrase banks, guided speaking, and explained answers.

Revised 2026 edition / Upper-intermediate to advanced

Your route through the book

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02 Assay Development and Reproducibility, page 15

Explain within-run precision separately from between-day variation and request a traceable investigation.

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04 Preclinical Data Packages, page 39

Summarize a nonclinical finding with its design and limitations, then identify missing information for the next review.

05 CMC and Scale-Up in Biotech, page 54

Distinguish titer, recovered quantity, product quality, and scale-up evidence in a process-transfer discussion.

06 IP, Freedom to Operate, and Collaboration, page 65

Identify unresolved material-use and publication terms while keeping ownership, permission, and freedom to operate distinct.

07 Investor and Board Updates, page 79

Connect completed work to a scientific funding criterion and explain a conditional cash-runway calculation.

08 Partnering and Business Development, page 90

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Suggested study range: B2-C1. This is an editorial study range, not a certified proficiency assessment.

A promising signal needs a precise claim.

Biotechnology teams must explain specialized results to colleagues who make different kinds of decisions. A scientist asks whether the assay supports the mechanism; a development lead asks what remains untested; a partner asks what rights and evidence are actually available. The conversations here keep the scientific detail while making those decision boundaries explicit.

Name the experimental system

State which model, material, readout, and comparison support the finding. A result in one setting can justify further investigation without proving a platform works across every proposed use.

"We observed the signal in one cell line; the broader application remains a hypothesis."

Expand the word validated

Say what was evaluated, for which intended use, against which criteria, and with what remaining limits. Analytical performance and a useful clinical decision are different claims.

"The assay measures the analyte in the assessed range; clinical prediction has not been established."

Make the next decision visible

A list of completed experiments is not a decision-ready update. Connect each result to the milestone criterion, the unresolved question, and the proposed next allocation of time or resources.

"The binding work is complete; the functional criterion remains open."

Define rights before promising access

Materials, confidential information, patents, know-how, and resulting data are different things. Identify the proposed use and unresolved terms before assuming that one agreement grants every permission.

"The confidentiality agreement does not settle the material-use or publication terms."

Professional boundaries

Original fictional language practice, not experimental instructions or medical, regulatory, legal, or investment advice. All organizations, candidates, numerical examples, and negotiations are invented. Apply current scientific standards, local procedures, appropriate professional review, and the actual governing agreements.

A Read the situation

LESSON 01 / PLATFORM TECHNOLOGY AND SCIENTIFIC THESIS

Distinguish a measured platform signal from a proposed mechanism and a broader development hypothesis.

One cell line, three proposed diseases

Research lead Nia reviews a fictional platform presentation with venture lead Leo. Three independent preparations of one cell line show an average reporter-signal reduction of 40% against the stated control. No orthogonal functional result or data from other disease systems are available. The slide claims proven activity across three diseases. The immediate request is funding for a bounded follow-up study, not approval for clinical use. Nia and Leo must retain the promising observation while correcting the unsupported breadth.

People: Nia, Research lead; Leo, Venture lead.

Read the record

Choose one answer per question using the facts above.

1. Which evidence is supplied?

- A.** Confirmed benefit in three diseases
- B.** A completed human efficacy study
- C.** Functional confirmation from an orthogonal assay
- D.** A 40% average reporter-signal reduction in three independent preparations of one cell line

2. Which claim exceeds that evidence?

- A.** A signal observed in the stated cell line
- B.** Three independent preparations tested
- C.** A follow-up study proposed
- D.** Proven activity across three diseases

3. What is the immediate decision request?

- A.** Authorizing clinical use
- B.** Declaring every platform application validated
- C.** Licensing all disease rights without review
- D.** Funding a bounded follow-up study

[Answers and explanations, page 118](#)

B Vocabulary in use

CORE TERMS

platform technology

A reusable technological approach intended to support multiple applications.

develop a platform technology

modality

A type of therapeutic or technological approach.

compare therapeutic modalities

target engagement

Evidence that an intervention interacts with its intended biological target.

assess target engagement

reporter signal

A measurable output used as an indicator in an experimental system.

quantify a reporter signal

biological replicate

An independently prepared biological sample or experimental unit.

include biological replicates

control condition

A comparison used to interpret an experimental result.

specify the control condition

scientific thesis

The evidence-based argument and hypotheses underlying a research program.

articulate the scientific thesis

target

The biological entity a program aims to affect.

define the target

mechanism of action

The biological process through which an intervention produces an effect.

investigate the mechanism of action

cell line

A maintained population of cells used for research.

characterize the cell line

technical replicate

A repeated measurement of the same biological material or preparation.

distinguish technical replicates

orthogonal assay

A different measurement approach used to examine the same underlying question.

run an orthogonal assay

Say it in context

Stress the highlighted expression. Keep the surrounding words connected; pause at the end of the phrase.

platform technology PLATFORM TECHNOLOGY

develop a platform technology

Keep the meaning precise: A reusable technological approach intended to support multiple applications.

mechanism of action MECHANISM OF ACTION

investigate the mechanism of action

Keep the meaning precise: The biological process through which an intervention produces an effect.

B Precision and professional shorthand

EXTEND YOUR RANGE

functional readout

A measurement of a relevant biological activity or outcome.

confirm a functional readout

counter-screen

A separate screen used to identify unwanted or misleading effects.

include a counter-screen

off-target effect

An effect involving an unintended biological target or pathway.

evaluate off-target effects

proof of mechanism

Evidence supporting the proposed causal biological mechanism.

seek proof of mechanism

disease model

An experimental system representing selected aspects of a disease.

qualify the disease model

evidence gap

A missing piece of information relevant to a claim or decision.

identify an evidence gap

assay interference

An effect on the measurement system that can distort the apparent result.

investigate assay interference

selectivity

Preference for the intended target or effect relative to alternatives.

assess selectivity

proof of concept

Evidence supporting feasibility within a specified scope.

define the proof-of-concept scope

generalizability

The extent to which a finding applies beyond the tested setting.

assess generalizability

translational hypothesis

A proposed link between experimental findings and a later development setting.

test a translational hypothesis

decision gate

A defined point at which evidence is reviewed against criteria.

set a decision gate

Say it in context

Stress the highlighted expression. Keep the surrounding words connected; pause at the end of the phrase.

orthogonal assay ORTHOGONAL ASSAY

run an orthogonal assay

Keep the meaning precise: A different measurement approach used to examine the same underlying question.

off-target effect OFF-TARGET EFFECT

evaluate off-target effects

Keep the meaning precise: An effect involving an unintended biological target or pathway.

Phrases that move the work forward

Lead with the observation

We observed a 40% average reduction in the reporter signal.

Limit the breadth

Other disease systems have not yet been tested.

Keep the hypothesis

The broader platform application remains a testable hypothesis.

Check interference

Could the signal reflect an effect on the assay rather than the intended biology?

Avoid a mechanism claim

We have not established the full mechanism from this result alone.

Identify the gap

The missing evidence is functional confirmation in a relevant additional system.

Keep replication precise

These are independent preparations, not repeated reads presented as independent samples.

Bound the ask

We are requesting the next research step, not clinical authorization.

Name the system

The data come from three independent preparations of one cell line.

Separate signal from function

The reporter result does not yet establish the functional effect.

Request another method

We need a different readout to examine the underlying question.

Describe the control

The percentage is relative to the control specified in this experiment.

State the opportunity

The signal is promising enough to justify a focused next study.

Define the decision

The next study should answer whether this application merits further development.

Correct the slide

Replace proven across three diseases with the result actually measured.

Close with criteria

Agree what evidence would support or stop the next stage.

Precision in real exchanges

Purpose: Separate signal from function

Useful wording: The reporter result does not yet establish the functional effect.

Purpose: Keep the hypothesis

Useful wording: The broader platform application remains a testable hypothesis.

D Choose the response that fits

Choose one response for each situation. Preserve the facts, the decision boundary, and the purpose of the exchange.

1. Which slide headline is best supported?

- A.** All off-target effects excluded.
- B.** Reporter signal reduced by an average 40% in the tested cell line; broader applications remain untested.
- C.** Platform efficacy proven across three diseases.
- D.** Human benefit confirmed by three preparations.

2. One preparation is read three times with the same method. How should those reads be described?

- A.** Three biological replicates from three separate preparations
- B.** Three orthogonal assays confirming the mechanism
- C.** Three disease models demonstrating broader applicability
- D.** Three technical measurements of one biological preparation

3. A colleague needs the term for this meaning: The biological entity a program aims to affect. Which term fits?

- A.** disease model
- B.** counter-screen
- C.** biological replicate
- D.** target

D Choose the response that fits / continued

4. Rebuild the exchange from "One cell line, three proposed diseases". Leo: "The slide currently turns the three preparations into a visual with three disease labels. I can see how that could imply that each disease has been tested." Nia: [missing response] Leo: "What would you say about the mechanism? The lower signal looks consistent with the proposed pathway, but the headline makes the connection sound settled." Which response belongs in the gap?

- A.** Yes, as evidence relevant to the scientific thesis. We should explain the proposed applications while separating what we observed from what we expect to test next.
- B.** That makes the evidence gap visible. We still lack functional confirmation and data in other disease systems, so those limits should travel with the headline.
- C.** Keep the biological replicate description explicit. Three independent preparations tell us something about that system; they do not create evidence for three separate indications.
- D.** We do not yet have proof of mechanism. The reporter finding supports investigation, but an effect on the measurement system could also influence the apparent result.

[Answers and explanations, page 118](#)

One useful distinction

Three independent preparations provide information about variation within the tested biological system. They are not three diseases or three clinical trials. A reporter signal can support a research direction without establishing the full mechanism or proving human benefit.

E Conversation

One cell line, three proposed diseases

One cell line, three proposed diseases

Complete the numbered gaps. Use each bank entry once; some entries contain several words.

WORD AND PHRASE BANK

reporter signal / orthogonal assay / generalizability / assay interference / decision gate / scientific thesis / translational hypothesis / proof of mechanism / biological replicate / evidence gap

- 01 **Leo:** The headline says our platform has proven activity across three diseases. It sounds strong, but I want to know whether each part of that claim is supported.
- 02 **Nia:** We have a ¹ _____ reduction averaging forty percent against the specified control. The work used three independent preparations of one cell line, not three disease systems.
- 03 **Leo:** Can we still call it a platform result? The investors need to see why this is more than a single isolated observation with no development direction.
- 04 **Nia:** Yes, as evidence relevant to the ² _____. We should explain the proposed applications while separating what we observed from what we expect to test next.
- 05 **Leo:** The slide currently turns the three preparations into a visual with three disease labels. I can see how that could imply that each disease has been tested.
- 06 **Nia:** Keep the ³ _____ description explicit. Three independent preparations tell us something about that system; they do not create evidence for three separate indications.

E Conversation / continued

- 07 **Leo:** What would you say about the mechanism? The lower signal looks consistent with the proposed pathway, but the headline makes the connection sound settled.
- 08 **Nia:** We do not yet have ⁴ _____. The reporter finding supports investigation, but an effect on the measurement system could also influence the apparent result.
- 09 **Leo:** What would the next study tell us that another reporter run would not? The funding request needs a scientific question, not just a larger sample count.
- 10 **Nia:** It should include an ⁵ _____ addressing the underlying biology. A different measurement approach would help distinguish a relevant biological effect from a feature of this reporter system.

Conversation continues on the next page.

One cell line, three proposed diseases

CONVERSATION / CONTINUED

- 11 **Leo:** We should be clear that you are asking to test that distinction, not promising that the second method will confirm the first. Otherwise the milestone is misleading.
- 12 **Nia:** Correct. We also need to assess ⁶ _____ and the appropriate controls. A promising decrease is not sufficient to dismiss competing explanations for the measured change.
- 13 **Leo:** How do we describe the proposed disease expansion without making it sound like a result? I want an ambitious but defensible sentence in the investor discussion.
- 14 **Nia:** Call it a ⁷ _____ and name the additional systems we propose to evaluate. The audience can understand the opportunity without being told that unperformed work has succeeded.
- 15 **Leo:** I will keep the forty-percent observation in the main line and put the tested system beside it. The expansion will be a proposed application, not a proven one.
- 16 **Nia:** That makes the ⁸ _____ visible. We still lack functional confirmation and data in other disease systems, so those limits should travel with the headline.
- 17 **Leo:** For the decision itself, we want a bounded research budget, not a commitment to take every suggested indication into development. The proposal needs a stopping point.
- 18 **Nia:** Set a ⁹ _____ with agreed evidence criteria. We should know what question the work will answer and how that answer affects the next development choice.
- 19 **Leo:** I will remove the three-disease claim and request the bounded follow-up. Keep the forty-percent result beside the actual cell system so the claim cannot drift again.
- 20 **Nia:** Good. That preserves the platform ambition while keeping ¹⁰ _____ open to investigation. We can be confident about the observation without claiming that every future application already works.

CHECK THE GAPS

1. reporter signal / 2. scientific thesis / 3. biological replicate / 4. proof of mechanism / 5. orthogonal assay / 6. assay interference / 7. translational hypothesis / 8. evidence gap / 9. decision gate / 10. generalizability

[Why these answers fit, page 119](#)

F Check accuracy and scope

One cell line, three proposed diseases

Return to the case

Research lead Nia reviews a fictional platform presentation with venture lead Leo. Three independent preparations of one cell line show an average reporter-signal reduction of 40% against the stated control. No orthogonal functional result or data from other disease systems are available. The slide claims proven activity across three diseases. The immediate request is funding for a bounded follow-up study, not approval for clinical use. Nia and Leo must retain the promising observation while correcting the unsupported breadth.

Choose one answer per question. Use the case facts and keep any uncertainty or limits intact.

1. Why request an orthogonal functional readout?

- A. To guarantee a favorable outcome
- B. To avoid describing the original control
- C. To examine the biological question through a different measurement approach
- D. To relabel the same reporter result as clinical evidence

2. Which funding request matches the brief?

- A. Authorize clinical use because the signal is promising.
- B. Assume all diseases will respond and skip further evidence.
- C. Treat three preparations as completed trials in three indications.
- D. Support a bounded follow-up addressing functional confirmation and broader relevance.

[Answers and explanations, page 121](#)

Listen for the distinction

Swap roles. Contrast a technical repeat with an orthogonal method; retain the untested broader applications.

Precision can strengthen a pitch

A confident scientific presentation distinguishes observation, interpretation, and the next test. Qualifying a claim does not require burying the result. Put the system and limitation beside the headline so a listener can understand both the promise and the reason for the next study.

F Say it / transfer to a new case

One model is not every model

A screening result is observed in one cell model. Two other proposed models have not been tested. The team requests a study of those additional systems.

Complete the four gaps. With a partner, read alternate roles, then switch. Studying alone, read both roles and pause before each response.

WORD AND PHRASE BANK

hypothesis / model / untested / gap

- 01 **Scientist:** The signal was observed in one ¹ _____.
- 02 **Partner:** The other two are still ² _____.
- 03 **Scientist:** Broader application remains a ³ _____.
- 04 **Partner:** The next study should address that evidence ⁴ _____.

CHECK THE GAPS

1. model / 2. untested / 3. hypothesis / 4. gap

[Why these answers fit, page 121](#)

Rebuild the exchange

Choose the missing response. Read the completed three-turn exchange aloud, changing roles on the second reading.

1. Rebuild the exchange from "One cell line, three proposed diseases". Leo: "How do we describe the proposed disease expansion without making it sound like a result? I want an ambitious but defensible sentence in the investor discussion." Nia: [missing response] Leo: "I will keep the forty-percent observation in the main line and put the tested system beside it. The expansion will be a proposed application, not a proven one." Which response belongs in the gap?

- A. We have a reporter signal reduction averaging forty percent against the specified control. The work used three independent preparations of one cell line, not three disease systems.
- B. It should include an orthogonal assay addressing the underlying biology. A different measurement approach would help distinguish a relevant biological effect from a feature of this reporter system.
- C. Good. That preserves the platform ambition while keeping generalizability open to investigation. We can be confident about the observation without claiming that every future application already works.
- D. Call it a translational hypothesis and name the additional systems we propose to evaluate. The audience can understand the opportunity without being told that unperformed work has succeeded.

[Answers and explanations, page 122](#)

A Read the situation

LESSON 02 / ASSAY DEVELOPMENT AND REPRODUCIBILITY

Explain within-run precision separately from between-day variation and request a traceable investigation.

Tight wells, shifting days

Assay scientist Imani and project lead Chen review a fictional control sample measured over three days. Each day has a within-run coefficient of variation of 5%, but the day means are 80, 100, and 125 signal units. The same nominal control level was intended each day. The summary says fully reproducible. Reagent-lot, calibration, and operator records still need comparison. No acceptance limits or confirmed cause are supplied; the team must describe the variation without inventing a validation decision.

People: Imani, Assay scientist; Chen, Project lead.

Read the record

Choose one answer per question using the facts above.

1. What is consistent within each run?

- A. A common acceptance limit has been met.
- B. The stated coefficient of variation is 5%.
- C. Every day mean is 100.
- D. Every reagent lot has been verified identical.

2. What changes across days?

- A. The mean signal: 80, 100, and 125 units
- B. The supplied acceptance limit
- C. The number of confirmed disease indications
- D. The definition of an independent clinical trial

3. What cannot yet be concluded?

- A. A confirmed cause or full validation status
- B. That day three has a mean of 125
- C. That the within-run CV is supplied
- D. That records need comparison

[Answers and explanations, page 123](#)

B Vocabulary in use

CORE TERMS

assay development

Designing and refining a measurement method for a specified purpose.

plan assay development

intermediate precision

Precision with relevant changes within one laboratory, such as day or operator.

evaluate intermediate precision

within-run variation

Differences among measurements within a single analytical run.

quantify within-run variation

coefficient of variation

Standard deviation divided by the mean, often expressed as a percentage.

report the coefficient of variation

mean signal

The average measured output for a defined group.

compare mean signals

accuracy

Closeness of a measurement to the relevant reference or accepted value.

evaluate analytical accuracy

repeatability

Precision under closely matched conditions over a short interval.

assess repeatability

reproducibility

Precision under specified changed conditions, commonly across laboratories.

define reproducibility conditions

between-day variation

Differences associated with measurements on different days.

investigate between-day variation

standard deviation

A measure of how observations are spread around their mean.

calculate the standard deviation

precision

Closeness among repeated measurements under stated conditions.

assess analytical precision

bias

A systematic difference from the relevant reference value.

investigate measurement bias

Say it in context

Stress the highlighted expression. Keep the surrounding words connected; pause at the end of the phrase.

assay development **ASSAY DEVELOPMENT**

plan assay development

Keep the meaning precise: Designing and refining a measurement method for a specified purpose.

between-day variation **BETWEEN-DAY VARIATION**

investigate between-day variation

Keep the meaning precise: Differences associated with measurements on different days.

B Precision and professional shorthand

EXTEND YOUR RANGE

calibration

Establishing the relationship between measurement response and reference values.

verify calibration records

quality-control sample

A sample used to monitor analytical performance.

review quality-control samples

lot-to-lot variation

Differences associated with separate batches of a material.

evaluate lot-to-lot variation

edge effect

A position-related difference at the outer wells of a plate.

check for an edge effect

normalization

Adjusting results to a defined comparison or reference basis.

document normalization

root-cause investigation

A structured effort to identify supported underlying explanations.

conduct a root-cause investigation

reference standard

A characterized material used to support measurement comparisons.

qualify a reference standard

reagent lot

An identified production batch of a reagent.

compare reagent lots

plate effect

Variation associated with a measurement plate or its positions.

assess a plate effect

assay drift

A change in measurement performance over time.

monitor assay drift

acceptance criterion

A predefined requirement for judging a result or process.

specify acceptance criteria

run metadata

Information describing the conditions and history of an analytical run.

preserve run metadata

Say it in context

Stress the highlighted expression. Keep the surrounding words connected; pause at the end of the phrase.

bias BIAS

investigate measurement bias

Keep the meaning precise: A systematic difference from the relevant reference value.

lot-to-lot variation LOT-TO-LOT VARIATION

evaluate lot-to-lot variation

Keep the meaning precise: Differences associated with separate batches of a material.

Phrases that move the work forward

Separate the levels

The within-run precision is consistent, but the day means differ.

Define the statistic

The CV describes relative spread within each run.

Ask for the criteria

Which predefined acceptance criteria apply to this intended use?

Preserve the raw result

Keep the original measurements and their run records.

Avoid premature blame

We have not established which factor explains the shift.

Name the percentage base

Twenty-five above one hundred is a 25% increase relative to one hundred.

Keep normalization justified

State the reference and method used for any adjustment.

Report the status

Between-day variation is under investigation.

Give the values

The means are eighty, one hundred, and one hundred twenty-five signal units.

Limit the conclusion

That does not establish agreement across days.

Check the comparison

Was the same nominal control level used in each run?

Investigate conditions

Compare reagent lots, calibration, operator, and relevant run conditions.

Explain precision

Tight measurements can still differ systematically from a reference.

Challenge the label

Fully reproducible is broader than these data support.

Request traceability

Link the plotted mean to its raw data and metadata.

Close with the question

The next review must explain the shift and evaluate it against the agreed criteria.

Precision in real exchanges

Purpose: Limit the conclusion

Useful wording: That does not establish agreement across days.

Purpose: Ask for the criteria

Useful wording: Which predefined acceptance criteria apply to this intended use?

D Choose the response that fits

Choose one response for each situation. Preserve the facts, the decision boundary, and the purpose of the exchange.

1. Which statement fits the data?

- A.** The operator caused the shift, as already established.
- B.** Each run has 5% CV, while day means differ from 80 to 125 units.
- C.** A 5% CV proves the same mean every day.
- D.** The assay is clinically validated because the means are positive.

2. Relative to day two's mean of 100, how much higher is day three's mean of 125?

- A.** 25%
- B.** 5%
- C.** 20%
- D.** 125%

3. A colleague needs the term for this meaning: Precision under specified changed conditions, commonly across laboratories. Which term fits?

- A.** normalization
- B.** reproducibility
- C.** mean signal
- D.** quality-control sample

D Choose the response that fits / continued

4. Rebuild the exchange from "Tight wells, shifting days". Chen: "We intended the same nominal control level. Could the newest operator explain the shift? That was the first suggestion in yesterday's meeting." Imani: [missing response] Chen: "Right. If the operator and reagent lot changed together, the pattern would not isolate either one. I should not report an attribution we cannot defend." Which response belongs in the gap?

- A.** We are examining intermediate precision within this laboratory. State the days and conditions examined so the reader does not infer an interlaboratory study.
- B.** Agreed. Include the calibration records too, so we can trace the measurement basis rather than infer it from the graph alone.
- C.** Use day two as the base. The mean signal increased twenty-five percent: twenty-five divided by one hundred. Twenty percent describes the reverse decrease.
- D.** Let us compare the run metadata first: operator, reagent lot, calibration and relevant conditions. We do not yet know which changes coincide.

[Answers and explanations, page 123](#)

One useful distinction

A 5% within-run coefficient of variation describes relative spread inside that run. It does not establish matching means across days or accuracy against a reference. Without supplied acceptance criteria, the exercise cannot declare the assay validated or failed.

E Conversation

Tight wells, shifting days

Tight wells, shifting days

Complete the numbered gaps. Use each bank entry once; some entries contain several words.

WORD AND PHRASE BANK

acceptance criterion / within-run variation / run metadata / mean signal /
intermediate precision / root-cause investigation / normalization / calibration /
coefficient of variation / precision

- 01 **Chen:** Every run has a five-percent CV, so I kept fully reproducible in the summary. What am I missing before we show this to the project team?
- 02 **Imani:** The ¹ _____ is similar, but the means are eighty, one hundred, and one hundred twenty-five. The runs do not sit at the same level.
- 03 **Chen:** So the points can be tightly grouped each day while the groups move? I treated the repeated percentage as evidence of an unchanged result.
- 04 **Imani:** The ² _____ is standard deviation divided by mean. Five percent describes relative spread; it does not tell us that the means match.
- 05 **Chen:** We intended the same nominal control level. Could the newest operator explain the shift? That was the first suggestion in yesterday's meeting.
- 06 **Imani:** Let us compare the ³ _____ first: operator, reagent lot, calibration and relevant conditions. We do not yet know which changes coincide.
- 07 **Chen:** Right. If the operator and reagent lot changed together, the pattern would not isolate either one. I should not report an attribution we cannot defend.
- 08 **Imani:** Keep both as questions in the ⁴ _____. The point is to test explanations against the records, not settle on the most convenient person to blame.
- 09 **Chen:** All three runs were in this laboratory. Is between-day reproducibility the clearest heading, or would another term make the conditions more precise?
- 10 **Imani:** We are examining ⁵ _____ within this laboratory. State the days and conditions examined so the reader does not infer an interlaboratory study.

Conversation continues on the next page.

Tight wells, shifting days

CONVERSATION / CONTINUED

- 11 **Chen:** I also wrote that day three rose twenty percent from day two. I divided twenty-five by the final value of one hundred twenty-five.
- 12 **Imani:** Use day two as the base. The ⁶ _____ increased twenty-five percent: twenty-five divided by one hundred. Twenty percent describes the reverse decrease.
- 13 **Chen:** Thanks. Is the shift enough to call the assay failed? I cannot find the intended-use limits in this review pack.
- 14 **Imani:** We need the applicable ⁷ _____. Do not invent a pass or failure threshold from this chart; report the between-day difference as under investigation.
- 15 **Chen:** Someone offered to rescale every day's mean to one hundred. It would remove the visible shift, but would it resolve the performance question?
- 16 **Imani:** Not by itself. Any ⁸ _____ needs a justified reference and documented method. An adjustment chosen only to align these means can hide what needs investigation.
- 17 **Chen:** Then retain the original readings and show how any adjusted result was derived. The unadjusted plot should not disappear from the package.
- 18 **Imani:** Agreed. Include the ⁹ _____ records too, so we can trace the measurement basis rather than infer it from the graph alone.
- 19 **Chen:** I will show the three means beside their CVs, correct the percentage, and list the missing criteria and records. No validation conclusion yet.
- 20 **Imani:** That gives ¹⁰ _____ its proper scope. We retain the useful within-run result while making the unresolved between-day performance visible.

CHECK THE GAPS

1. within-run variation / 2. coefficient of variation / 3. run metadata / 4. root-cause investigation / 5. intermediate precision / 6. mean signal / 7. acceptance criterion / 8. normalization / 9. calibration / 10. precision

[Why these answers fit, page 124](#)

F Check accuracy and scope

Tight wells, shifting days

Return to the case

Assay scientist Imani and project lead Chen review a fictional control sample measured over three days. Each day has a within-run coefficient of variation of 5%, but the day means are 80, 100, and 125 signal units. The same nominal control level was intended each day. The summary says fully reproducible. Reagent-lot, calibration, and operator records still need comparison. No acceptance limits or confirmed cause are supplied; the team must describe the variation without inventing a validation decision.

Choose one answer per question. Use the case facts and keep any uncertainty or limits intact.

1. Which follow-up best supports investigation?

- A. Compare traceable run conditions and raw data before assigning a cause.
- B. Delete the two means that differ from 100.
- C. Declare every run acceptable without criteria.
- D. Rename the axis to conceal the shift.

2. A colleague rescales each day to a mean of 100 and calls the assay reproducible. What remains unresolved?

- A. Whether the rescaled means are numerically equal to each other
- B. Whether the three original runs occurred on different days
- C. Whether the adjusted chart now uses the same vertical scale
- D. Whether the adjustment has a justified basis and the original between-day variation is understood

[Answers and explanations, page 126](#)

Listen for the distinction

Swap roles. Correct the denominator: 100 to 125 is a 25% increase; 125 to 100 is a 20% decrease.

Ask which kind of consistency

A colleague may use reproducible as a broad compliment while an assay specialist means a defined set of conditions. Clarify the tested source of variation rather than argue about the word alone. Numbers become useful when the comparison, units, and experimental structure are visible.

F Say it / transfer to a new case

A percentage needs its reference

Two comparable fictional runs have means of 120 and 150 units. Their within-run CVs are both 4%. No acceptance criteria are supplied.

Complete the four gaps. With a partner, read alternate roles, then switch. Studying alone, read both roles and pause before each response.

WORD AND PHRASE BANK

thirty / spread / criteria / 25%

- 01 **Analyst:** The mean rose by ¹ _____ units.
- 02 **Reviewer:** Relative to 120, that is a ² _____ increase.
- 03 **Analyst:** The four-percent CV describes within-run ³ _____.
- 04 **Reviewer:** A formal acceptance decision still needs the applicable ⁴ _____.

CHECK THE GAPS

1. thirty / 2. 25% / 3. spread / 4. criteria

[Why these answers fit, page 126](#)

Rebuild the exchange

Choose the missing response. Read the completed three-turn exchange aloud, changing roles on the second reading.

1. Rebuild the exchange from "Tight wells, shifting days". Chen: "Thanks. Is the shift enough to call the assay failed? I cannot find the intended-use limits in this review pack." Imani: [missing response] Chen: "Someone offered to rescale every day's mean to one hundred. It would remove the visible shift, but would it resolve the performance question?" Which response belongs in the gap?

- A.** The within-run variation is similar, but the means are eighty, one hundred, and one hundred twenty-five. The runs do not sit at the same level.
- B.** We are examining intermediate precision within this laboratory. State the days and conditions examined so the reader does not infer an interlaboratory study.
- C.** The coefficient of variation is standard deviation divided by mean. Five percent describes relative spread; it does not tell us that the means match.
- D.** We need the applicable acceptance criterion. Do not invent a pass or failure threshold from this chart; report the between-day difference as under investigation.

[Answers and explanations, page 127](#)

Review 1 / Meaning and context

Use language from the lessons you have completed. Choose one answer per question.

Case file

Revisit "Platform Technology and Scientific Thesis" and "Assay Development and Reproducibility". Choose precise terminology, then reconstruct the missing responses using both neighboring turns. The final two questions also revisit earlier conversations.

1. A colleague needs the term for this meaning: A type of therapeutic or technological approach. Which term fits?

- A. generalizability
- B. modality
- C. cell line
- D. assay interference

2. A colleague needs the term for this meaning: A measure of how observations are spread around their mean. Which term fits?

- A. calibration
- B. edge effect
- C. assay development
- D. standard deviation

3. Rebuild the exchange from "One cell line, three proposed diseases". Leo: "What would the next study tell us that another reporter run would not? The funding request needs a scientific question, not just a larger sample count." Nia: [missing response] Leo: "We should be clear that you are asking to test that distinction, not promising that the second method will confirm the first. Otherwise the milestone is misleading." Which response belongs in the gap?

- A. Good. That preserves the platform ambition while keeping generalizability open to investigation. We can be confident about the observation without claiming that every future application already works.
- B. It should include an orthogonal assay addressing the underlying biology. A different measurement approach would help distinguish a relevant biological effect from a feature of this reporter system.
- C. We have a reporter signal reduction averaging forty percent against the specified control. The work used three independent preparations of one cell line, not three disease systems.
- D. Call it a translational hypothesis and name the additional systems we propose to evaluate. The audience can understand the opportunity without being told that unperformed work has succeeded.

Review 1 / Meaning and context / continued

4. Rebuild the exchange from "Tight wells, shifting days". Chen: "Then retain the original readings and show how any adjusted result was derived. The unadjusted plot should not disappear from the package." Imani: [missing response] Chen: "I will show the three means beside their CVs, correct the percentage, and list the missing criteria and records. No validation conclusion yet." Which response belongs in the gap?

- A.** We are examining intermediate precision within this laboratory. State the days and conditions examined so the reader does not infer an interlaboratory study.
- B.** Use day two as the base. The mean signal increased twenty-five percent: twenty-five divided by one hundred. Twenty percent describes the reverse decrease.
- C.** Agreed. Include the calibration records too, so we can trace the measurement basis rather than infer it from the graph alone.
- D.** Let us compare the run metadata first: operator, reagent lot, calibration and relevant conditions. We do not yet know which changes coincide.

[Answers and explanations, page 158](#)

A Read the situation

LESSON 03 / BIOMARKERS AND TRANSLATIONAL STRATEGY

Specify the scope of biomarker validation and distinguish measurement performance from response prediction.

Validated for which use?

Translational lead Sara and assay lead Noah review a fictional plasma-protein test. The analytical study met its predefined measurement criteria over 2 to 20 research units in the tested plasma conditions. No study has established that the protein predicts response to candidate B17. A slide calls it a validated predictive biomarker and proposes selecting trial participants by its value. The team must correct that claim and identify the intended-use evidence still needed. No patient-selection rule is authorized by the exercise.

People: Sara, Translational lead; Noah, Assay lead.

Read the record

Choose one answer per question using the facts above.

1. Which claim is supported by the supplied study?

- A. Regulatory qualification has been granted.
- B. The test met predefined analytical criteria over the assessed range and plasma conditions.
- C. The protein predicts B17 response.
- D. A patient-selection threshold has clinical support.

2. What evidence is absent?

- A. The existence of predefined measurement criteria
- B. A study establishing prediction of response to B17
- C. The fact that plasma was tested
- D. The stated analytical range

3. Which proposed use requires additional support?

- A. Stating the tested range
- B. Reporting the analytical study's actual scope
- C. Selecting participants on an asserted predictive role
- D. Describing the measured analyte

[Answers and explanations, page 128](#)

B Vocabulary in use

CORE TERMS

biomarker

A measured characteristic indicating a biological process or response.

evaluate a biomarker

context of use

The defined purpose and setting in which a biomarker is to be used.

specify the context of use

clinical validation

Establishing the relationship to the relevant clinical concept for the proposed use.

plan clinical validation

biomarker qualification

Formal acceptance for a specified use through an applicable qualification process.

define the qualification scope

reportable range

The interval over which results can be appropriately reported under the method.

specify the reportable range

limit of quantification

The lowest level measurable with specified quantitative performance.

establish a limit of quantification

analyte

The substance or component a test measures.

identify the analyte

analytical validation

Establishing that a test adequately measures its intended analyte for the stated use.

complete analytical validation

clinical utility

The usefulness of applying a test in a particular care decision.

assess clinical utility

fit for purpose

Adequate for a specifically defined intended use.

demonstrate fit-for-purpose performance

limit of detection

The lowest level distinguishable from absence under defined conditions.

establish a limit of detection

matrix effect

An influence of other sample components on the measurement.

assess matrix effects

Say it in context

Stress the highlighted expression. Keep the surrounding words connected; pause at the end of the phrase.

biomarker **BIOMARKER**

evaluate a biomarker

Keep the meaning precise: A measured characteristic indicating a biological process or response.

clinical utility **CLINICAL UTILITY**

assess clinical utility

Keep the meaning precise: The usefulness of applying a test in a particular care decision.

B Precision and professional shorthand

EXTEND YOUR RANGE

diagnostic sensitivity

The proportion of people with the target condition correctly identified as positive.

estimate diagnostic sensitivity

positive predictive value

The proportion of positive test results that correspond to the target condition.

interpret positive predictive value

prevalence

The proportion of the relevant population with a condition at a stated time.

account for prevalence

prognostic biomarker

A marker associated with likelihood of a clinical event or disease progression.

distinguish a prognostic biomarker

pharmacodynamic biomarker

A marker indicating biological response after exposure to an intervention.

measure a pharmacodynamic biomarker

prospective validation

Testing performance in a study planned before the relevant outcomes are observed.

design prospective validation

diagnostic specificity

The proportion without the target condition correctly identified as negative.

estimate diagnostic specificity

negative predictive value

The proportion of negative results that correspond to absence of the target condition.

interpret negative predictive value

decision threshold

A specified cutoff used in making a defined classification or decision.

justify a decision threshold

predictive biomarker

A marker identifying differing likelihood of an effect from a particular intervention.

evaluate a predictive biomarker

patient stratification

Grouping patients by defined characteristics for analysis or an intended use.

justify patient stratification

external validation

Evaluation in an independent setting or data source.

obtain external validation

Say it in context

Stress the highlighted expression. Keep the surrounding words connected; pause at the end of the phrase.

matrix effect MATRIX EFFECT

assess matrix effects

Keep the meaning precise: An influence of other sample components on the measurement.

prevalence PREVALENCE

account for prevalence

Keep the meaning precise: The proportion of the relevant population with a condition at a stated time.

Phrases that move the work forward

Ask for the scope

Validated for which measurement and intended use?

Name the range

The assessed measurement range is two to twenty research units.

Separate the claims

Analytical performance does not establish prediction of treatment response.

Avoid premature selection

We do not yet have evidence supporting that predictive selection rule.

Clarify qualification

A study result is not automatically formal biomarker qualification.

Separate prognosis

Association with disease course is not necessarily prediction of treatment effect.

Preserve uncertainty

The relationship to B17 response remains unestablished.

Identify the next evidence

The next study must address the intended clinical relationship.

State the analyte

The test measures the specified protein in plasma.

Preserve the conditions

That evidence applies to the tested plasma conditions.

Define the purpose

The proposed use is participant selection for the B17 program.

Use the correct label

Describe an analytically evaluated test, not a clinically validated predictive biomarker.

Ask about the cohort

Which population and outcomes would establish the claimed relationship?

Check the cutoff

What supports the proposed decision threshold?

Compare samples carefully

Performance in plasma does not automatically transfer to another sample matrix.

Close the slide review

Keep the measurement result and the proposed clinical use in separate statements.

Precision in real exchanges

Purpose: Preserve the conditions

Useful wording: That evidence applies to the tested plasma conditions.

Purpose: Separate the claims

Useful wording: Analytical performance does not establish prediction of treatment response.

D Choose the response that fits

Choose one response for each situation. Preserve the facts, the decision boundary, and the purpose of the exchange.

1. Which description matches the supplied evidence?

- A.** The protein is qualified for every clinical use.
- B.** A result above ten guarantees benefit.
- C.** The test met analytical criteria from 2 to 20 research units; prediction of B17 response is unestablished.
- D.** The test selects all B17 responders reliably.

2. Why is a predictive label premature?

- A.** The analyte is measured in plasma.
- B.** A measurement range was defined.
- C.** The analytical criteria were predefined.
- D.** No study has established differing B17 response associated with the marker.

3. A colleague needs the term for this meaning: Establishing that a test adequately measures its intended analyte for the stated use. Which term fits?

- A.** reportable range
- B.** pharmacodynamic biomarker
- C.** positive predictive value
- D.** analytical validation

D Choose the response that fits / continued

4. Rebuild the exchange from "Validated for which use?". Sara: "We should state the planned decision explicitly, then. The proposed use is selecting participants for the B17 program, not simply reporting protein concentration in a research sample." Noah: [missing response] Sara: "What should replace validated predictive biomarker in the current deck? I do not want to lose the analytical achievement while correcting the clinical overstatement." Which response belongs in the gap?

- A.** No. A prognostic biomarker concerns the likely clinical course. That association would not by itself establish that the marker identifies a differing effect of this intervention.
- B.** That is the context of use that needs supporting evidence. A reliable measurement can be necessary without being sufficient for the clinical decision being proposed.
- C.** It establishes the assessed analytical validation scope: the test met predefined measurement criteria from two to twenty research units in the plasma conditions we evaluated.
- D.** Name the analyte, tested matrix, and range, then state that response prediction remains unestablished. We can report the achievement accurately without borrowing a broader label.

[Answers and explanations, page 128](#)

One useful distinction

Analytical validation concerns the measurement; clinical validation concerns the proposed clinical relationship. Clinical utility asks a further question about using the result in a decision. None of these labels should be inferred solely from another label or from an attractive plot.

E Conversation

Validated for which use?

Validated for which use?

Complete the numbered gaps. Use each bank entry once; some entries contain several words.

WORD AND PHRASE BANK

analytical validation / prognostic biomarker / clinical utility / analyte / clinical validation / Biomarker qualification / matrix effect / decision threshold / predictive biomarker / context of use

- 01 **Sara:** The slide says validated predictive biomarker and then proposes selecting participants by the protein value. Can you tell me which part of that statement our study establishes?
- 02 **Noah:** It establishes the assessed ¹ _____ scope: the test met predefined measurement criteria from two to twenty research units in the plasma conditions we evaluated.
- 03 **Sara:** That is useful, but it does not tell us whether a participant with a particular value is more likely to respond to B17 than another participant.
- 04 **Noah:** Correct. We have not established ² _____ for that proposed relationship. The measurement study did not test whether the marker identifies differences in response to this candidate.
- 05 **Sara:** We should state the planned decision explicitly, then. The proposed use is selecting participants for the B17 program, not simply reporting protein concentration in a research sample.
- 06 **Noah:** That is the ³ _____ that needs supporting evidence. A reliable measurement can be necessary without being sufficient for the clinical decision being proposed.

E Conversation / continued

- 07 **Sara:** What should replace validated predictive biomarker in the current deck? I do not want to lose the analytical achievement while correcting the clinical overstatement.
- 08 **Noah:** Name the ⁴ _____, tested matrix, and range, then state that response prediction remains unestablished. We can report the achievement accurately without borrowing a broader label.
- 09 **Sara:** Why did the team choose ten units as the cutoff? Being inside the measurement range does not tell us who is likely to respond to B17.
- 10 **Noah:** A ⁵ _____ needs a justified relationship to the intended decision. The assay's ability to measure a value does not tell us what that value means for response.

Conversation continues on the next page.

Validated for which use?

CONVERSATION / CONTINUED

- 11 **Sara:** Suppose another study later associates the protein with faster disease progression. Would that automatically make it predictive for B17?
- 12 **Noah:** No. A ⁶ _____ concerns the likely clinical course. That association would not by itself establish that the marker identifies a differing effect of this intervention.
- 13 **Sara:** The distinction needs to appear in our terminology sheet. People use predict in everyday English for almost any association with a later event.
- 14 **Noah:** In this development claim, a ⁷ _____ relates to the effect of a particular intervention. We should define the intended scientific meaning rather than assume the everyday word settles it.
- 15 **Sara:** Another team wants to transfer the assay to a different sample type. They believe the protein name being unchanged means the measurement evidence transfers automatically.
- 16 **Noah:** We need to evaluate possible ⁸ _____ and the changed conditions. The same analyte in another sample environment is not automatically covered by the plasma performance study.
- 17 **Sara:** And an internal study meeting its criteria is not the same as receiving formal acceptance for every possible regulatory use. We should remove qualified from that sentence too.
- 18 **Noah:** Yes. ⁹ _____ has an applicable process and defined scope. We should not imply that such a determination exists when the evidence described here does not establish one.

Validated for which use? / continued

- 19 **Sara:** I will remove validated predictive biomarker and the implied selection rule. Please give me wording that preserves the analytical result and names the clinical question still open.
- 20 **Noah:** Then later we can also assess ¹⁰ _____ for the relevant decision. For now, accurate measurement is a defined achievement, and the clinical application remains a separate evidence question.

CHECK THE GAPS

1. analytical validation / 2. clinical validation / 3. context of use / 4. analyte / 5. decision threshold / 6. prognostic biomarker / 7. predictive biomarker / 8. matrix effect / 9. Biomarker qualification / 10. clinical utility

[Why these answers fit, page 129](#)

F Check accuracy and scope

Validated for which use?

Return to the case

Translational lead Sara and assay lead Noah review a fictional plasma-protein test. The analytical study met its predefined measurement criteria over 2 to 20 research units in the tested plasma conditions. No study has established that the protein predicts response to candidate B17. A slide calls it a validated predictive biomarker and proposes selecting trial participants by its value. The team must correct that claim and identify the intended-use evidence still needed. No patient-selection rule is authorized by the exercise.

Choose one answer per question. Use the case facts and keep any uncertainty or limits intact.

1. A colleague chooses 11 as an eligibility cutoff because it is the midpoint of 2 to 20. What evidence is missing?

- A. Evidence that 11 lies inside the assessed measurement range
- B. Evidence that the midpoint of 2 and 20 equals 11
- C. Evidence that the analytical study used plasma samples
- D. Evidence supporting classification by that cutoff for the proposed B17 use

2. What would changing the sample from plasma require in the claim?

- A. Assuming identical performance because the analyte has the same name
- B. Calling the new matrix clinically validated without data
- C. Removing all information about sample conditions
- D. Appropriate evaluation of the changed matrix rather than automatic transfer of performance

[Answers and explanations, page 131](#)

Listen for the distinction

Swap roles. Distinguish measuring the protein from predicting B17 response; do not create an eligibility rule.

A qualifier should identify the claim

Validated is persuasive because it sounds complete. Ask what was validated, in which material and range, and for which intended use. These questions help colleagues align scientific and clinical claims without treating the person who raised the issue as an obstacle to progress.

F Say it / transfer to a new case

Measurement is not selection

A test measures a protein adequately from 5 to 50 study units. No relationship to treatment response has been studied. A colleague proposes using 25 as an eligibility cutoff.

Complete the four gaps. With a partner, read alternate roles, then switch. Studying alone, read both roles and pause before each response.

WORD AND PHRASE BANK

selection / unstudied / range / threshold

- 01 **Scientist:** Five to fifty is the assessed measurement ¹ _____.
- 02 **Colleague:** Twenty-five is a proposed decision ² _____.
- 03 **Scientist:** Its relationship to response is ³ _____.
- 04 **Colleague:** The analytical result does not authorize participant ⁴ _____.

CHECK THE GAPS

1. range / 2. threshold / 3. unstudied / 4. selection

[Why these answers fit, page 131](#)

Rebuild the exchange

Choose the missing response. Read the completed three-turn exchange aloud, changing roles on the second reading.

1. Rebuild the exchange from "Validated for which use?". Sara: "The distinction needs to appear in our terminology sheet. People use predict in everyday English for almost any association with a later event." Noah: [missing response] Sara: "Another team wants to transfer the assay to a different sample type. They believe the protein name being unchanged means the measurement evidence transfers automatically." Which response belongs in the gap?

- A.** Then later we can also assess clinical utility for the relevant decision. For now, accurate measurement is a defined achievement, and the clinical application remains a separate evidence question.
- B.** A decision threshold needs a justified relationship to the intended decision. The assay's ability to measure a value does not tell us what that value means for response.
- C.** Yes. Biomarker qualification has an applicable process and defined scope. We should not imply that such a determination exists when the evidence described here does not establish one.
- D.** In this development claim, a predictive biomarker relates to the effect of a particular intervention. We should define the intended scientific meaning rather than assume the everyday word settles it.

[Answers and explanations, page 132](#)

A Read the situation

LESSON 04 / PRECLINICAL DATA PACKAGES

Summarize a nonclinical finding with its design and limitations, then identify missing information for the next review.

A model effect is not proof of human benefit

A fictional animal-model report compares 12 treated animals with 12 controls and reports a 20% lower mean model-endpoint value at one tested exposure. Groups were randomized; assessor blinding is not documented in the supplied summary. No uncertainty interval, exposure-response series, or human outcome data are provided. Scientist Amir and development lead Zoe review a slide calling the result proof of human benefit. They need a precise nonclinical summary and the missing study details, not an invented clinical conclusion.

People: Amir, Scientist; Zoe, Development lead.

Read the record

Choose one answer per question using the facts above.

1. What is the reported comparison?

- A. Identical results across every tested exposure
- B. A completed clinical trial in 24 patients
- C. A 20% lower mean model-endpoint value in 12 treated animals versus 12 controls at one exposure
- D. A 20% improvement in human survival

2. What is known about blinding?

- A. The assessors were definitely unblinded.
- B. Randomization automatically establishes blinding.
- C. It is not documented in the supplied summary.
- D. The assessors were definitely blinded.

3. Which conclusion is unsupported?

- A. The groups were randomized.
- B. One exposure was tested.
- C. Further study details are needed.
- D. Human benefit has been proved.

[Answers and explanations, page 133](#)

B Vocabulary in use

CORE TERMS

preclinical package

The body of nonclinical evidence supporting a development review.

assemble a preclinical package

sex as a biological variable

Consideration of sex-related differences in design, analysis, and reporting.

address sex as a biological variable

blinding

Keeping relevant group or treatment information hidden from specified people.

verify assessor blinding

experimental unit

The independently assigned unit underlying an experimental comparison.

identify the experimental unit

pharmacodynamics

The biological effects of an intervention and their relationship to exposure.

evaluate pharmacodynamics

exposure-response relationship

The relationship between measured exposure and an observed effect.

examine the exposure-response relationship

model relevance

How an experimental system relates to the biological question of interest.

assess model relevance

randomization

Allocation by a chance-based process to reduce systematic selection differences.

document randomization

sample size

The number of experimental units in a defined analysis.

justify the sample size

pharmacokinetics

The time course of a substance's absorption, distribution, metabolism, and elimination.

characterize pharmacokinetics

exposure

The amount or concentration reaching a biological system over time.

characterize exposure

bioavailability

Rate and extent of systemic availability of an active substance.

assess bioavailability

Say it in context

Stress the highlighted expression. Keep the surrounding words connected; pause at the end of the phrase.

preclinical package PRECLINICAL PACKAGE

assemble a preclinical package

Keep the meaning precise: The body of nonclinical evidence supporting a development review.

sample size SAMPLE SIZE

justify the sample size

Keep the meaning precise: The number of experimental units in a defined analysis.

B Precision and professional shorthand

EXTEND YOUR RANGE

biodistribution

The pattern of a substance's presence across tissues or body compartments.

characterize biodistribution

tolerability

How adverse effects affect the ability to tolerate an intervention.

report tolerability findings

NOAEL

No-observed-adverse-effect level under the conditions of a defined study.

interpret the NOAEL in context

good laboratory practice

A formal quality system for applicable nonclinical safety studies.

verify good laboratory practice status

translational uncertainty

Uncertainty in applying findings from one biological setting to another.

communicate translational uncertainty

efficacy endpoint

A defined measurement used to assess the intended effect in a study.

specify the efficacy endpoint

toxicology

Study of harmful effects of substances under specified conditions.

review toxicology data

safety margin

A comparison of relevant exposure or dose levels used in safety assessment.

justify the safety-margin comparison

dose-response relationship

The relationship between administered dose and a measured effect.

distinguish dose-response from exposure-response

study report

The documented methods, results, and interpretation of a study.

review the full study report

B Precision and professional shorthand / continued

data provenance

The origin and processing history of data used in a result.

preserve data provenance

uncertainty interval

A stated range expressing uncertainty under a defined analytical method.

report the uncertainty interval

Say it in context

Stress the highlighted expression. Keep the surrounding words connected; pause at the end of the phrase.

bioavailability BIOAVAILABILITY

assess bioavailability

Keep the meaning precise: Rate and extent of systemic availability of an active substance.

NOAEL NOAEL

interpret the NOAEL in context

Keep the meaning precise: No-observed-adverse-effect level under the conditions of a defined study.

Phrases that move the work forward

Name the model result

The treated group had a 20% lower mean model-endpoint value than controls.

Identify the tested condition

The result comes from one tested exposure.

Separate design features

Randomization is documented; assessor blinding is not stated in this summary.

Ask about uncertainty

Which interval or analysis describes uncertainty around the reported difference?

Name the missing relationship

We do not yet have an exposure-response series.

Clarify PK and PD

Distinguish the exposure measurements from the biological response.

Preserve unit definitions

Identify the experimental units behind the reported sample size.

Avoid an invented margin

We cannot calculate a human safety margin from these facts alone.

State the groups

There were twelve treated animals and twelve controls.

Keep the species boundary

Human benefit has not been established by these data.

Request the source

Please provide the full report and the relevant analysis details.

Avoid a significance claim

The supplied percentage alone does not establish statistical significance.

Keep safety separate

An efficacy-endpoint result does not establish the complete safety profile.

Check study status

Do not infer formal GLP compliance from the word preclinical.

Limit the translation

This supports further investigation within a defined development question.

Close the package review

Summarize the finding, its limits, and the specific evidence still required.

Precision in real exchanges

Purpose: Keep the species boundary

Useful wording: Human benefit has not been established by these data.

Purpose: Separate design features

Useful wording: Randomization is documented; assessor blinding is not stated in this summary.

D Choose the response that fits

Choose one response for each situation. Preserve the facts, the decision boundary, and the purpose of the exchange.

1. Which sentence best represents the result?

- A.** At one exposure, the treated animal group had a 20% lower mean model endpoint than controls; human benefit is unestablished.
- B.** Humans improve by 20% with this intervention.
- C.** The treatment is proven safe at every exposure.
- D.** Blinded human efficacy was confirmed.

2. What does the missing blinding information mean?

- A.** The review needs clarification from the study record.
- B.** Randomization proves the assessors were blinded.
- C.** The study definitely had no blinding.
- D.** The endpoint can be described as independently replicated in humans.

3. A colleague needs the term for this meaning: Allocation by a chance-based process to reduce systematic selection differences. Which term fits?

- A.** tolerability
- B.** pharmacodynamics
- C.** translational uncertainty
- D.** randomization

D Choose the response that fits / continued

4. Rebuild the exchange from "A model effect is not proof of human benefit". Zoe: "I see randomized allocation, but nothing about assessor blinding. Can you obtain that record before anyone adds blinded to the summary?" Amir: [missing response] Zoe: "I will request that detail from the study team. An omission in this summary does not prove the assessors knew the assignments, but it leaves the status unclear." Which response belongs in the gap?

- A.** The efficacy endpoint mean was twenty percent lower in twelve treated animals than in twelve controls. That is the comparison the study summary actually reports.
- B.** Yes. Review the relevant toxicology and other safety evidence separately. We should not infer a complete safety profile from an endpoint designed to assess the intended effect.
- C.** Agreed. The model relevance needs explanation, but relevance does not make the model identical to human disease. No human outcome data are included in this package.
- D.** Randomization and assessor blinding are separate design features. The first is documented here; the second is not stated, so we need clarification rather than an assumption.

[Answers and explanations, page 133](#)

One useful distinction

A 20% lower model-endpoint mean is not automatically a 20% clinical benefit or a statistically established effect. State the comparison and missing uncertainty information. Randomization and blinding are distinct design features; one does not establish the other.

E Conversation

A model effect is not proof of human benefit

A model effect is not proof of human benefit

Complete the numbered gaps. Use each bank entry once; some entries contain several words.

WORD AND PHRASE BANK

study report / toxicology / pharmacokinetics / Randomization / translational uncertainty / exposure-response relationship / model relevance / safety margin / uncertainty interval / efficacy endpoint

- 01 **Zoe:** The development slide says this is proof of human benefit. The reported model effect is encouraging, but I need a sentence that will survive a detailed package review.
- 02 **Amir:** The ¹ _____ mean was twenty percent lower in twelve treated animals than in twelve controls. That is the comparison the study summary actually reports.
- 03 **Zoe:** We should say it was an animal model in the headline, not leave the audience to find that in a footnote after hearing a clinical claim.
- 04 **Amir:** Agreed. The ² _____ needs explanation, but relevance does not make the model identical to human disease. No human outcome data are included in this package.
- 05 **Zoe:** I see randomized allocation, but nothing about assessor blinding. Can you obtain that record before anyone adds blinded to the summary?
- 06 **Amir:** ³ _____ and assessor blinding are separate design features. The first is documented here; the second is not stated, so we need clarification rather than an assumption.

E Conversation / continued

- 07 **Zoe:** I will request that detail from the study team. An omission in this summary does not prove the assessors knew the assignments, but it leaves the status unclear.
- 08 **Amir:** Ask for the relevant ⁴ _____ section and any supporting record. We should correct the summary from verified information, not fill the gap with the most favorable wording.
- 09 **Zoe:** The twenty-percent difference also appears without an interval. I cannot tell how much uncertainty surrounds the estimate from the headline alone.
- 10 **Amir:** We need the appropriate ⁵ _____ or other specified analysis and the underlying results. A percentage by itself does not establish statistical significance or the reliability of the estimate.

Conversation continues on the next page.

A model effect is not proof of human benefit

CONVERSATION / CONTINUED

- 11 **Zoe:** The team tested one exposure. That can establish a result under that condition, but it cannot show the whole pattern across lower and higher exposures.
- 12 **Amir:** Correct. We do not yet have an ⁶ _____. Keep that limitation beside the result so the development discussion does not assume a series that was never performed.
- 13 **Zoe:** We also need to separate an administered dose from what reaches the relevant biological system. Those terms are being used interchangeably in the notes.
- 14 **Amir:** The ⁷ _____ information addresses the disposition and exposure over time. The biological effect belongs to the pharmacodynamic question; neither can be replaced by a vague statement that the dose worked.
- 15 **Zoe:** What about the sentence saying the favorable endpoint establishes safety? I assume the full safety question requires different information and appropriate professional review.
- 16 **Amir:** Yes. Review the relevant ⁸ _____ and other safety evidence separately. We should not infer a complete safety profile from an endpoint designed to assess the intended effect.
- 17 **Zoe:** Nor should we invent a human safety margin from this one model result. We do not have the necessary comparison or its scientific justification.
- 18 **Amir:** Exactly. Any ⁹ _____ must state the compared quantities and supporting basis. A reassuring label cannot supply the missing exposure information or translation rationale.
- 19 **Zoe:** I will keep the result explicitly nonclinical and request the missing uncertainty and exposure information. Please also confirm the blinding status from the study records.
- 20 **Amir:** That communicates ¹⁰ _____ without discarding the finding. The result can justify further investigation while remaining distinct from proof that people will benefit.

CHECK THE GAPS

1. efficacy endpoint / 2. model relevance / 3. Randomization / 4. study report / 5. uncertainty interval / 6. exposure-response relationship / 7. pharmacokinetics / 8. toxicology / 9. safety margin / 10. translational uncertainty

[Why these answers fit, page 135](#)

F Check accuracy and scope

A model effect is not proof of human benefit

Return to the case

A fictional animal-model report compares 12 treated animals with 12 controls and reports a 20% lower mean model-endpoint value at one tested exposure. Groups were randomized; assessor blinding is not documented in the supplied summary. No uncertainty interval, exposure-response series, or human outcome data are provided. Scientist Amir and development lead Zoe review a slide calling the result proof of human benefit. They need a precise nonclinical summary and the missing study details, not an invented clinical conclusion.

Choose one answer per question. Use the case facts and keep any uncertainty or limits intact.

1. Which addition would directly clarify uncertainty around the reported 20% model-endpoint difference?

- A. Confirmation that both groups contained twelve animals, without their results
- B. The reported randomization method alone, without variability or analysis
- C. The proposed human population, without additional model-study results
- D. The underlying group results and a justified uncertainty analysis

2. Which distinction is accurate?

- A. Administered dose and measured exposure are related but not identical concepts.
- B. One tested exposure establishes every dose-response relationship.
- C. An efficacy endpoint is the complete toxicology package.
- D. Formal GLP status follows automatically from using animals.

[Answers and explanations, page 136](#)

Listen for the distinction

Swap roles. State blinding not documented rather than blinded or unblinded; request the relevant study record.

Report what the study can carry

Development discussions reward concise conclusions, but a short sentence should still name the model, comparison, and limits. Separate a positive result from a claim about people. Asking for missing design information strengthens the review without implying that the study was necessarily conducted badly.

F Say it / transfer to a new case

An omission is not a finding

A study summary documents random allocation but does not describe assessor blinding. A colleague proposes writing either fully blinded or definitely unblinded without checking the report.

Complete the four gaps. With a partner, read alternate roles, then switch. Studying alone, read both roles and pause before each response.

WORD AND PHRASE BANK

record / unstated / verification / allocation

- 01 **Scientist:** Random ¹ _____ is documented.
- 02 **Reviewer:** Assessor blinding remains ² _____.
- 03 **Scientist:** We need the relevant study ³ _____.
- 04 **Reviewer:** Neither proposed label is supported without ⁴ _____.

CHECK THE GAPS

1. allocation / 2. unstated / 3. record / 4. verification

[Why these answers fit, page 136](#)

F Say it / transfer to a new case / continued

Rebuild the exchange

Choose the missing response. Read the completed three-turn exchange aloud, changing roles on the second reading.

1. Rebuild the exchange from "A model effect is not proof of human benefit". Zoe: "We also need to separate an administered dose from what reaches the relevant biological system. Those terms are being used interchangeably in the notes." Amir: [missing response] Zoe: "What about the sentence saying the favorable endpoint establishes safety? I assume the full safety question requires different information and appropriate professional review." Which response belongs in the gap?

- A.** Correct. We do not yet have an exposure-response relationship. Keep that limitation beside the result so the development discussion does not assume a series that was never performed.
- B.** Ask for the relevant study report section and any supporting record. We should correct the summary from verified information, not fill the gap with the most favorable wording.
- C.** The pharmacokinetics information addresses the disposition and exposure over time. The biological effect belongs to the pharmacodynamic question; neither can be replaced by a vague statement that the dose worked.
- D.** We need the appropriate uncertainty interval or other specified analysis and the underlying results. A percentage by itself does not establish statistical significance or the reliability of the estimate.

[Answers and explanations, page 137](#)

Review 2 / Meaning and context

Use language from the lessons you have completed. Choose one answer per question.

Case file

Revisit "Biomarkers and Translational Strategy" and "Preclinical Data Packages". Choose precise terminology, then reconstruct the missing responses using both neighboring turns. The final two questions also revisit earlier conversations.

1. A colleague needs the term for this meaning: The defined purpose and setting in which a biomarker is to be used. Which term fits?

- A. predictive biomarker
- B. fit for purpose
- C. diagnostic specificity
- D. context of use

2. A colleague needs the term for this meaning: The time course of a substance's absorption, distribution, metabolism, and elimination. Which term fits?

- A. pharmacokinetics
- B. biodistribution
- C. good laboratory practice
- D. preclinical package

3. Rebuild the exchange from "Tight wells, shifting days". Chen: "All three runs were in this laboratory. Is between-day reproducibility the clearest heading, or would another term make the conditions more precise?" Imani: [missing response] Chen: "I also wrote that day three rose twenty percent from day two. I divided twenty-five by the final value of one hundred twenty-five." Which response belongs in the gap?

- A. We are examining intermediate precision within this laboratory. State the days and conditions examined so the reader does not infer an interlaboratory study.
- B. The coefficient of variation is standard deviation divided by mean. Five percent describes relative spread; it does not tell us that the means match.
- C. Use day two as the base. The mean signal increased twenty-five percent: twenty-five divided by one hundred. Twenty percent describes the reverse decrease.
- D. Let us compare the run metadata first: operator, reagent lot, calibration and relevant conditions. We do not yet know which changes coincide.

Review 2 / Meaning and context / continued

4. Rebuild the exchange from "A model effect is not proof of human benefit". Zoe: "Nor should we invent a human safety margin from this one model result. We do not have the necessary comparison or its scientific justification." Amir: [missing response] Zoe: "I will keep the result explicitly nonclinical and request the missing uncertainty and exposure information. Please also confirm the blinding status from the study records." Which response belongs in the gap?

- A.** Agreed. The model relevance needs explanation, but relevance does not make the model identical to human disease. No human outcome data are included in this package.
- B.** Exactly. Any safety margin must state the compared quantities and supporting basis. A reassuring label cannot supply the missing exposure information or translation rationale.
- C.** The efficacy endpoint mean was twenty percent lower in twelve treated animals than in twelve controls. That is the comparison the study summary actually reports.
- D.** That communicates translational uncertainty without discarding the finding. The result can justify further investigation while remaining distinct from proof that people will benefit.

[Answers and explanations, page 161](#)

A Read the situation

LESSON 05 / CMC AND SCALE-UP IN BIOTECH

Distinguish titer, recovered quantity, product quality, and scale-up evidence in a process-transfer discussion.

Two small runs do not prove the large process

Process scientist Hana and manufacturing lead Ben review two fictional 1-liter runs after a process transfer. Both achieved a harvest titer of 0.8 grams per liter. A 200-liter run has not been performed. The slide promises 160 grams of finished acceptable product by multiplying titer by volume. Downstream recovery and relevant quality results at the larger scale are unestablished. The team must retain the small-run result while correcting the forecast and defining the missing scale-up evidence.

People: Hana, Process scientist; Ben, Manufacturing lead.

Read the record

Choose one answer per question using the facts above.

1. What was demonstrated?

- A. A successful 200-liter run
- B. Complete quality comparability at all scales
- C. Harvest titer of 0.8 g/L in two 1-liter runs
- D. Release of 160 grams of finished product

2. What does 0.8 g/L multiplied by 200 liters give under the stated assumption?

- A. A 160% recovery rate
- B. A validated clinical dose
- C. A hypothetical 160 grams at harvest before downstream losses
- D. A guaranteed 160 grams of released finished product

3. Which evidence remains missing?

- A. Whether two small runs occurred
- B. The small-run titer value
- C. The proposed large-run volume
- D. Larger-scale performance, downstream recovery, and relevant quality results

[Answers and explanations, page 138](#)

B Vocabulary in use

CORE TERMS

CMC

Chemistry, manufacturing, and controls: the product and process quality package.

review the CMC package

upstream processing

The production stages that generate the biological material.

characterize upstream processing

titer

Product concentration at a specified process stage.

report harvest titer

recovery

The proportion of material retained through a specified process step.

calculate downstream recovery

potency

A measure of biological activity relevant to the product's function.

evaluate product potency

critical quality attribute

A property needing control within appropriate limits to ensure desired quality.

identify critical quality attributes

technology transfer

Movement of process knowledge and capability between teams or sites.

execute technology transfer

downstream processing

Stages that recover and purify material after production.

evaluate downstream processing

yield

Output relative to a stated input or theoretical basis, with context required.

define the yield basis

purity

The proportion or profile of intended material relative to impurities.

assess product purity

aggregation

Association of molecules into larger assemblies.

monitor product aggregation

critical process parameter

A process variable whose variability can affect a critical quality attribute.

assess critical process parameters

Say it in context

Stress the highlighted expression. Keep the surrounding words connected; pause at the end of the phrase.

CMC CMC

review the CMC package

Keep the meaning precise: Chemistry, manufacturing, and controls: the product and process quality package.

yield YIELD

define the yield basis

Keep the meaning precise: Output relative to a stated input or theoretical basis, with context required.

B Precision and professional shorthand

EXTEND YOUR RANGE

process parameter

A measurable or controlled operating variable in a process.

document process parameters

scale-up

Increasing the size or production capacity of a process.

evaluate scale-up risks

mass transfer

Movement of a substance between regions or phases of a system.

assess mass-transfer behavior

hold time

The time material remains at a specified stage or condition.

justify hold times

comparability

Assessment that a change does not adversely affect relevant product quality, safety, or efficacy.

establish a comparability strategy

process characterization

Study of how process conditions affect performance and quality.

plan process characterization

scale-down model

A smaller model intended to represent relevant larger-process behavior.

qualify a scale-down model

mixing

Distribution of material within a process vessel or system.

characterize mixing

bioburden

The level of viable microorganisms associated with a material or process.

monitor bioburden

change control

Formal review and management of a proposed change.

follow change control

B Precision and professional shorthand / continued

process validation

Documented evidence that a process can consistently deliver the intended quality.

plan process validation

batch record

The record of materials, steps, observations, and events for a batch.

review the batch record

Say it in context

Stress the highlighted expression. Keep the surrounding words connected; pause at the end of the phrase.

critical process parameter [CRITICAL PROCESS PARAMETER](#)

assess critical process parameters

Keep the meaning precise: A process variable whose variability can affect a critical quality attribute.

mass transfer [MASS TRANSFER](#)

assess mass-transfer behavior

Keep the meaning precise: Movement of a substance between regions or phases of a system.

Phrases that move the work forward

State the observed scale

Both results came from one-liter runs.

Show the arithmetic

At the same titer, two hundred liters would contain one hundred sixty grams at harvest.

Separate recovery

Downstream losses are not included in that calculation.

Clarify the acronym

CMC covers chemistry, manufacturing, and controls.

Avoid premature validation

Two small runs do not establish the complete larger-scale process.

Identify the evidence

We need relevant larger-scale performance and quality data.

Define the model

Which aspects of the large process does the small model represent?

Separate release

A projected quantity is not a release decision.

Name the stage

The measured value is harvest titer, not released final quantity.

Expose the assumption

The larger process has not yet demonstrated that titer.

Keep quality visible

Quantity alone does not establish purity or potency.

Ask about attributes

Which quality attributes need comparison after this change?

Check process behavior

Mixing and mass transfer may differ with scale.

Respect change review

Route the process change through the appropriate quality review.

Qualify the forecast

Present this as a conditional harvest estimate.

Close the transfer

Document the observed performance, open risks, and next agreed evaluation.

Precision in real exchanges

Purpose: Expose the assumption

Useful wording: The larger process has not yet demonstrated that titer.

Purpose: Separate recovery

Useful wording: Downstream losses are not included in that calculation.

D Choose the response that fits

Choose one response for each situation. Preserve the facts, the decision boundary, and the purpose of the exchange.

1. Which forecast is appropriately qualified?

- A.** The larger process is validated without being run.
- B.** If 0.8 g/L holds at 200 liters, harvest quantity would be 160 grams before recovery and quality evaluation.
- C.** Two small runs guarantee 160 grams of released product.
- D.** Titer alone proves complete comparability.

2. If a separate hypothetical process retains 70% of 160 grams, how much remains after that step?

- A.** 112 grams
- B.** 230 grams
- C.** 70 grams
- D.** 160 grams

3. A colleague needs the term for this meaning: Stages that recover and purify material after production. Which term fits?

- A.** scale-up
- B.** comparability
- C.** downstream processing
- D.** potency

D Choose the response that fits / continued

4. Rebuild the exchange from "Two small runs do not prove the large process". Ben: "What would change the amount after harvest? The table currently carries all 160 grams straight through purification without showing any loss." Hana: [missing response] Ben: "If a later run did match the concentration, could I at least use quality confirmed? The slide needs a short status for the review." Which response belongs in the gap?

- A.** It omits downstream recovery. We need the retained fraction for the relevant stages, not an implicit assumption that all harvested material reaches the end.
- B.** Correct. Potency addresses relevant biological activity. The concentration alone does not establish it, just as it does not describe the full impurity profile.
- C.** Matching concentration does not verify every critical quality attribute. A short status still has to preserve the relevant purity, activity, and other quality questions.
- D.** The measured titer was 0.8 grams per liter at harvest. We have not run 200 liters, and finished material is a different stage.

[Answers and explanations, page 138](#)

One useful distinction

At the same assumed titer, 0.8 grams per liter times 200 liters gives 160 grams at harvest. It does not establish downstream recovery, final purity, potency, or release. Titer is a concentration; always define the basis when using yield.

E Conversation

Two small runs do not prove the large process

Two small runs do not prove the large process

Complete the numbered gaps. Use each bank entry once; some entries contain several words.

WORD AND PHRASE BANK

titer / Potency / comparability / recovery / critical quality attribute / scale-up /
mass transfer / scale-down model / CMC / change control

- 01 **Ben:** I have a production slide promising 160 grams of acceptable finished product at 200 liters. That comes from the two one-liter runs. Can we support it?
- 02 **Hana:** The measured ¹ _____ was 0.8 grams per liter at harvest. We have not run 200 liters, and finished material is a different stage.
- 03 **Ben:** Then 160 is a correct multiplication with an unproven scale assumption. I also mislabeled where in the process that quantity would exist.
- 04 **Hana:** Yes. The ² _____ still needs evidence. Write conditional harvest estimate, not finished-product commitment, so the receiving team can see both limits.
- 05 **Ben:** What would change the amount after harvest? The table currently carries all 160 grams straight through purification without showing any loss.
- 06 **Hana:** It omits downstream ³ _____. We need the retained fraction for the relevant stages, not an implicit assumption that all harvested material reaches the end.
- 07 **Ben:** If a later run did match the concentration, could I at least use quality confirmed? The slide needs a short status for the review.
- 08 **Hana:** Matching concentration does not verify every ⁴ _____. A short status still has to preserve the relevant purity, activity, and other quality questions.
- 09 **Ben:** So an equal number of grams does not necessarily mean an equal biological effect. That distinction needs to survive when this becomes a commercial forecast.
- 10 **Hana:** Correct. ⁵ _____ addresses relevant biological activity. The concentration alone does not establish it, just as it does not describe the full impurity profile.

Conversation continues on the next page.

Two small runs do not prove the large process

CONVERSATION / CONTINUED

- 11 **Ben:** We are also changing vessel size. I do not want the scale discussion reduced to multiplying every small-run setting by two hundred.
- 12 **Hana:** The review needs relevant ⁶ _____ and mixing behavior. Larger volume can change process conditions; proportional arithmetic does not demonstrate equivalent performance.
- 13 **Ben:** Can we still use the small system to investigate risks? I do not want to discard two useful runs because they answer a narrower question.
- 14 **Hana:** We can establish what a ⁷ _____ represents. Its value depends on the relevant behavior demonstrated, not merely on using a smaller vessel.
- 15 **Ben:** I will attach the process versions and batch records to the transfer pack. Which route keeps the proposed changes and their review traceable?
- 16 **Hana:** Use ⁸ _____ and the applicable transfer process. The receiving team needs the actual settings, changes, and supporting records, not just the headline.
- 17 **Ben:** One last wording point: two matching titers do not support saying comparability demonstrated. We still lack the relevant larger-scale quality results.
- 18 **Hana:** Exactly. Establishing ⁹ _____ requires examining the consequences for the product. A single matching output is not the whole assessment.
- 19 **Ben:** The revised slide will say two one-liter runs at 0.8 grams per liter; 160 grams is hypothetical harvest output before recovery and quality evaluation.
- 20 **Hana:** That is a usable ¹⁰ _____ update. Keep finished acceptable output unconfirmed and name the remaining evidence needed before making that commitment.

CHECK THE GAPS

1. titer / 2. scale-up / 3. recovery / 4. critical quality attribute / 5. Potency / 6. mass transfer / 7. scale-down model / 8. change control / 9. comparability / 10. CMC

[Why these answers fit, page 139](#)

F Check accuracy and scope

Two small runs do not prove the large process

Return to the case

Process scientist Hana and manufacturing lead Ben review two fictional 1-liter runs after a process transfer. Both achieved a harvest titer of 0.8 grams per liter. A 200-liter run has not been performed. The slide promises 160 grams of finished acceptable product by multiplying titer by volume. Downstream recovery and relevant quality results at the larger scale are unestablished. The team must retain the small-run result while correcting the forecast and defining the missing scale-up evidence.

Choose one answer per question. Use the case facts and keep any uncertainty or limits intact.

1. Which item is a quality question rather than simply a quantity calculation?

- A. Whether two one-liter runs were reported
- B. Whether relevant potency and impurity attributes remain appropriate
- C. Whether 0.8 times 200 equals 160
- D. Whether the proposed volume is 200 liters

2. Both one-liter runs have the same titer. Which proposed summary overstates the demonstrated scope?

- A. Larger-scale recovery and quality evidence remain outstanding.
- B. The 160-gram figure assumes the titer holds at 200 liters.
- C. Matching titer establishes larger-scale quality comparability.
- D. Matching titer is one result from the small-run process.

[Answers and explanations, page 141](#)

Listen for the distinction

Swap roles. State 0.8 times 200 equals 160 grams before downstream recovery; do not claim release.

A calculation can be correct and the promise wrong

Operational audiences need quantities and delivery expectations, but an arithmetic projection must keep its assumptions visible. Clarify the process stage, recovery basis, and quality status. A useful estimate is conditional; it should not quietly become a commitment to release finished material.

F Say it / transfer to a new case

Concentration is not the final quantity

A hypothetical harvest contains 0.5 grams per liter in 100 liters. A stated downstream step retains 80% of the harvest material. No release decision is supplied.

Complete the four gaps. With a partner, read alternate roles, then switch. Studying alone, read both roles and pause before each response.

WORD AND PHRASE BANK

fifty / release / forty / separate

- 01 **Scientist:** The harvest contains ¹ _____ grams.
- 02 **Reviewer:** At eighty-percent recovery, ² _____ grams remain.
- 03 **Scientist:** That is a quantity calculation, not a ³ _____ decision.
- 04 **Reviewer:** Keep the relevant product-quality evidence ⁴ _____.

CHECK THE GAPS

1. fifty / 2. forty / 3. release / 4. separate

[Why these answers fit, page 141](#)

Rebuild the exchange

Choose the missing response. Read the completed three-turn exchange aloud, changing roles on the second reading.

1. Rebuild the exchange from "Two small runs do not prove the large process". Ben: "Can we still use the small system to investigate risks? I do not want to discard two useful runs because they answer a narrower question." Hana: [missing response] Ben: "I will attach the process versions and batch records to the transfer pack. Which route keeps the proposed changes and their review traceable?" Which response belongs in the gap?

- A.** Use change control and the applicable transfer process. The receiving team needs the actual settings, changes, and supporting records, not just the headline.
- B.** We can establish what a scale-down model represents. Its value depends on the relevant behavior demonstrated, not merely on using a smaller vessel.
- C.** Correct. Potency addresses relevant biological activity. The concentration alone does not establish it, just as it does not describe the full impurity profile.
- D.** The measured titer was 0.8 grams per liter at harvest. We have not run 200 liters, and finished material is a different stage.

[Answers and explanations, page 142](#)

A Read the situation

LESSON 06 / IP, FREEDOM TO OPERATE, AND COLLABORATION

Identify unresolved material-use and publication terms while keeping ownership, permission, and freedom to operate distinct.

A confidentiality agreement is not a material license

Two fictional research partners plan to exchange a nonclinical reference protein for three named bench assessments. A confidentiality agreement is signed, but the material-transfer terms remain a draft. Permitted use, onward transfer, publication review, and rights in new findings are unresolved. Scientist Julia asks counsel Ravi whether shipment can proceed and whether owning a related patent settles third-party rights. Their discussion identifies questions for the authorized review; it does not interpret a real agreement or approve a transfer.

People: Julia, Scientist; Ravi, Counsel.

Read the record

Choose one answer per question using the facts above.

1. Which agreement is signed?

- A. The final material-transfer agreement
- B. A worldwide exclusive development license
- C. A completed assignment of every future invention
- D. The confidentiality agreement

2. Which issue remains unresolved?

- A. Whether counsel has been asked for review
- B. Permitted use and publication review, among other material-transfer terms
- C. Whether a reference protein is proposed
- D. Whether three bench assessments are contemplated

3. What does ownership of a related patent establish about third-party rights here?

- A. It replaces the material-transfer review.
- B. It does not by itself establish freedom to operate.
- C. It automatically removes every third-party right.
- D. It authorizes every recipient use worldwide.

[Answers and explanations, page 143](#)

B Vocabulary in use

CORE TERMS

intellectual property

Legally recognized rights in inventions, works, marks, or other protected subject matter.

identify relevant intellectual property

foreground IP

New intellectual property arising from the collaboration under its agreed definitions.

address foreground IP

ownership

The legal holding of a right or asset.

clarify ownership

license

Permission to exercise specified rights under stated terms.

negotiate a license

territory

The geographic scope of a right or permission.

specify the territory

nonexclusive license

Permission that does not generally prevent granting similar rights to others.

discuss a nonexclusive license

background IP

Intellectual property brought into a collaboration, as defined by the agreement.

define background IP

inventorship

Legal identification of the people who contributed to a claimed invention.

assess inventorship

assignment

Transfer of ownership of specified rights.

distinguish an assignment from a license

field of use

The defined application area within which permission applies.

limit the field of use

exclusive license

Permission with defined exclusivity within its agreed scope.

define exclusive-license scope

confidentiality obligation

A duty concerning protection and permitted disclosure of information.

comply with confidentiality obligations

Say it in context

Stress the highlighted expression. Keep the surrounding words connected; pause at the end of the phrase.

intellectual property **INTELLECTUAL PROPERTY**

identify relevant intellectual property

Keep the meaning precise: Legally recognized rights in inventions, works, marks, or other protected subject matter.

assignment **ASSIGNMENT**

distinguish an assignment from a license

Keep the meaning precise: Transfer of ownership of specified rights.

B Precision and professional shorthand

EXTEND YOUR RANGE

nondisclosure agreement

An agreement governing specified confidential information.

review a nondisclosure agreement

permitted use

The activities authorized for the material or rights under the agreement.

define permitted use

publication review

An agreed process for reviewing proposed public disclosure.

specify publication review

patent claim

The legal wording defining the scope of protection sought or granted.

review relevant patent claims

freedom to operate

Whether proposed acts can proceed without infringing relevant third-party rights.

obtain a scoped freedom-to-operate review

third-party rights

Rights held by someone outside the parties to the proposed arrangement.

assess third-party rights

material transfer agreement

An agreement governing the transfer and use of tangible research material.

finalize a material transfer agreement

onward transfer

Passing material or rights to another recipient.

address onward transfer

publication embargo

A stated restriction or delay on publication under applicable terms.

define a publication embargo

patentability

Whether an invention meets the applicable criteria for patent protection.

assess patentability

know-how

Practical technical information or expertise, sometimes protected as confidential information.

identify transferred know-how

governing agreement

The contract whose applicable terms control the relevant relationship or activity.

identify the governing agreement

Say it in context

Stress the highlighted expression. Keep the surrounding words connected; pause at the end of the phrase.

confidentiality obligation CONFIDENTIALITY OBLIGATION

comply with confidentiality obligations

Keep the meaning precise: A duty concerning protection and permitted disclosure of information.

publication review PUBLICATION REVIEW

specify publication review

Keep the meaning precise: An agreed process for reviewing proposed public disclosure.

Phrases that move the work forward

Identify the signed document

The confidentiality agreement is signed; the material-transfer terms are not final.

Separate permissions

Permission to receive information does not necessarily authorize use of the material.

Clarify new findings

How will rights in results and new inventions be addressed?

Protect publication

What review process and time limits apply before public disclosure?

Name existing rights

Identify the background IP each party brings.

Ask about third parties

Which relevant rights are held outside these two parties?

Avoid a patent shortcut

Owning our patent does not automatically establish freedom to operate.

Record the open terms

Keep permitted use and publication questions visible in the draft.

Define the activity

The proposed use is three named nonclinical bench assessments.

Check onward transfer

May the recipient send the material to another laboratory?

Separate inventorship

Inventorship and ownership should not be treated as interchangeable labels.

Avoid an unlimited delay

Publication review needs defined terms, not an unstated permanent veto.

Define the new work

Distinguish collaboration results from pre-existing know-how.

Scope FTO

The review needs the proposed acts, territories, and relevant time.

Reserve authorization

Shipment needs the appropriate completed review and authorization.

Close accurately

Scientific interest is aligned; the transfer terms remain unresolved.

Precision in real exchanges

Purpose: Check onward transfer

Useful wording: May the recipient send the material to another laboratory?

Purpose: Clarify new findings

Useful wording: How will rights in results and new inventions be addressed?

D Choose the response that fits

Choose one response for each situation. Preserve the facts, the decision boundary, and the purpose of the exchange.

1. Which response best fits the shipment question?

- A.** Shipment proves the terms were accepted in advance.
- B.** The MTA terms remain unresolved, so seek the required review and authorization before treating shipment as approved.
- C.** The signed NDA automatically approves every material use.
- D.** A common scientific goal replaces contract review.

2. Which review question concerns permitted use rather than a different transfer term?

- A.** How long may the provider review a proposed manuscript?
- B.** Who owns an invention arising from the collaboration?
- C.** Which named bench assessments may the recipient perform with the protein?
- D.** May the recipient send the protein to a third laboratory?

3. A colleague needs the term for this meaning: Legal identification of the people who contributed to a claimed invention. Which term fits?

- A.** inventorship
- B.** freedom to operate
- C.** permitted use
- D.** territory

D Choose the response that fits / continued

4. Rebuild the exchange from "A confidentiality agreement is not a material license".
Julia: "The intended work is limited to three named assessments. The recipient also mentioned asking a separate laboratory to help, which is not addressed in the draft." Ravi: [missing response] Julia: "We also need to clarify what happens to discoveries made during the evaluation. Each team is bringing existing methods and information to the work." Which response belongs in the gap?

- A.** Define the permitted use precisely and address any onward transfer. The scientific plan should match the scope being reviewed, including which organizations would actually handle the material.
- B.** Clarify any know-how being supplied and the authorized uses. Physical possession of a reference protein does not automatically settle rights in every method discussed alongside it.
- C.** Exactly. A nondisclosure agreement does not automatically answer every material-use question. We must examine the actual documents rather than assume the title grants whatever the project needs.
- D.** Correct. Inventorship and ownership are different legal questions. We should not resolve either casually in an email saying that every new idea belongs to the team.

[Answers and explanations, page 143](#)

One useful distinction

NDA means nondisclosure agreement; MTA means material transfer agreement; FTO means freedom to operate. Confidentiality, material permission, ownership, and third-party rights are different questions. The effect of any document depends on its actual language, scope, law, and circumstances.

E Conversation

A confidentiality agreement is not a material license

A confidentiality agreement is not a material license

Complete the numbered gaps. Use each bank entry once; some entries contain several words.

WORD AND PHRASE BANK

permitted use / governing agreement / background IP / know-how / third-party rights / freedom to operate / Inventorship / nondisclosure agreement / publication review / material transfer agreement

- 01 **Julia:** The partners agree on the science, and the confidentiality agreement is signed. Can I arrange shipment of the reference protein for the three bench assessments now?
- 02 **Ravi:** The ¹ _____ is still a draft. We need the relevant terms reviewed and authorized before treating the transfer as approved.
- 03 **Julia:** I had assumed the signed confidentiality document covered the exchange. It lets us discuss the work, but that may be different from permission to use the material.
- 04 **Ravi:** Exactly. A ² _____ does not automatically answer every material-use question. We must examine the actual documents rather than assume the title grants whatever the project needs.
- 05 **Julia:** The intended work is limited to three named assessments. The recipient also mentioned asking a separate laboratory to help, which is not addressed in the draft.
- 06 **Ravi:** Define the ³ _____ precisely and address any onward transfer. The scientific plan should match the scope being reviewed, including which organizations would actually handle the material.

Conversation / continued

- 07 **Julia:** We also need to clarify what happens to discoveries made during the evaluation. Each team is bringing existing methods and information to the work.
- 08 **Ravi:** Identify the ⁴ _____ separately from new results. The definitions should let both parties distinguish their existing rights from what the collaboration may generate.
- 09 **Julia:** If a new invention results, naming the people who contributed is not necessarily the same as deciding which organization will own the resulting rights.
- 10 **Ravi:** Correct. ⁵ _____ and ownership are different legal questions. We should not resolve either casually in an email saying that every new idea belongs to the team.

Conversation continues on the next page.

A confidentiality agreement is not a material license

CONVERSATION / CONTINUED

- 11 **Julia:** The recipient wants to publish. Can the draft specify how review would work, including timing, without implying either immediate unrestricted publication or an unlimited veto?
- 12 **Ravi:** Agree a defined ⁶ _____ process with the relevant purpose, timing, and consequences. Do not assume immediate unrestricted publication or an unlimited veto when neither term has been settled.
- 13 **Julia:** They also asked whether access to the material means they can use our practical methods in a later unrelated project. That sounds broader than this evaluation.
- 14 **Ravi:** Clarify any ⁷ _____ being supplied and the authorized uses. Physical possession of a reference protein does not automatically settle rights in every method discussed alongside it.
- 15 **Julia:** Our team owns a related patent. Some colleagues think that means we can tell the partner there are no intellectual-property obstacles to any proposed use.
- 16 **Ravi:** Ownership does not itself establish ⁸ _____. Other rights may matter, and the review needs the actual activity, territory, and relevant circumstances before anyone makes a clearance statement.
- 17 **Julia:** Then our own patentability work and a third-party-rights review should not be presented as the same assessment. They answer different questions for the collaboration.
- 18 **Ravi:** Yes. Examine relevant ⁹ _____ through appropriately scoped professional review. A right we hold is not a universal permission to practice every related technology or distribute every associated material.

A confidentiality agreement is not a material license / continued

- 19 **Julia:** I will hold shipment and send the exact assessment list and laboratory names for review. The teams agree on the science; the transfer terms still need resolution.
- 20 **Ravi:** That gives us a clear ¹⁰ _____ to finalize through the proper process. Once the terms and authorization are established, the team can act within that defined scope rather than rely on assumptions.

CHECK THE GAPS

1. material transfer agreement / 2. nondisclosure agreement / 3. permitted use / 4. background IP / 5. Inventorship / 6. publication review / 7. know-how / 8. freedom to operate / 9. third-party rights / 10. governing agreement

[Why these answers fit, page 144](#)

F Check accuracy and scope

A confidentiality agreement is not a material license

Return to the case

Two fictional research partners plan to exchange a nonclinical reference protein for three named bench assessments. A confidentiality agreement is signed, but the material-transfer terms remain a draft. Permitted use, onward transfer, publication review, and rights in new findings are unresolved. Scientist Julia asks counsel Ravi whether shipment can proceed and whether owning a related patent settles third-party rights. Their discussion identifies questions for the authorized review; it does not interpret a real agreement or approve a transfer.

Choose one answer per question. Use the case facts and keep any uncertainty or limits intact.

1. Why does a related owned patent not settle FTO?

- A. Patent ownership always means the patent is invalid.
- B. Every research material is automatically unprotected.
- C. An MTA can never contain use terms.
- D. Other parties may hold relevant rights affecting the proposed acts.

2. Which statement preserves the publication issue?

- A. A planned manuscript proves ownership of all inventions.
- B. The publication-review process and timing remain to be agreed.
- C. Every result may be published immediately because an NDA exists.
- D. Publication is forbidden forever regardless of the draft.

[Answers and explanations, page 146](#)

Listen for the distinction

Swap roles. Separate permitted use, onward transfer, publication review, and ownership; retain the unapproved shipment status.

A shared scientific aim does not settle the agreement

Researchers may use collaborate to mean anything from a limited evaluation to joint development. Define the intended work and the relevant rights before relying on that word. Asking about publication or ownership early can protect the relationship by exposing different expectations before materials move.

F Say it / transfer to a new case

Access to a file is not every right

A partner may receive a confidential method summary for evaluation. No permission for commercial use or onward disclosure has been agreed in the supplied facts.

Complete the four gaps. With a partner, read alternate roles, then switch. Studying alone, read both roles and pause before each response.

WORD AND PHRASE BANK

evaluation / unresolved / terms / permitted

- 01 **Scientist:** The stated purpose is ¹ _____.
- 02 **Partner:** Commercial use is not established as ² _____.
- 03 **Scientist:** Onward disclosure also remains ³ _____.
- 04 **Partner:** We need the actual governing ⁴ _____.

CHECK THE GAPS

1. evaluation / 2. permitted / 3. unresolved / 4. terms

[Why these answers fit, page 146](#)

Rebuild the exchange

Choose the missing response. Read the completed three-turn exchange aloud, changing roles on the second reading.

1. Rebuild the exchange from "A confidentiality agreement is not a material license".

Julia: "They also asked whether access to the material means they can use our practical methods in a later unrelated project. That sounds broader than this evaluation." **Ravi:** [missing response] **Julia:** "Our team owns a related patent. Some colleagues think that means we can tell the partner there are no intellectual-property obstacles to any proposed use." **Which response belongs in the gap?**

- A.** Correct. Inventorship and ownership are different legal questions. We should not resolve either casually in an email saying that every new idea belongs to the team.
- B.** Define the permitted use precisely and address any onward transfer. The scientific plan should match the scope being reviewed, including which organizations would actually handle the material.
- C.** Clarify any know-how being supplied and the authorized uses. Physical possession of a reference protein does not automatically settle rights in every method discussed alongside it.
- D.** Exactly. A nondisclosure agreement does not automatically answer every material-use question. We must examine the actual documents rather than assume the title grants whatever the project needs.

[Answers and explanations, page 147](#)

Review 3 / Meaning and context

Use language from the lessons you have completed. Choose one answer per question.

Case file

Revisit "CMC and Scale-Up in Biotech" and "IP, Freedom to Operate, and Collaboration". Choose precise terminology, then reconstruct the missing responses using both neighboring turns. The final two questions also revisit earlier conversations.

1. A colleague needs the term for this meaning: The production stages that generate the biological material. Which term fits?

- A. bioburden
- B. upstream processing
- C. purity
- D. process characterization

2. A colleague needs the term for this meaning: The defined application area within which permission applies. Which term fits?

- A. patent claim
- B. nondisclosure agreement
- C. field of use
- D. intellectual property

3. Rebuild the exchange from "A model effect is not proof of human benefit". Zoe: "The twenty-percent difference also appears without an interval. I cannot tell how much uncertainty surrounds the estimate from the headline alone." Amir: [missing response] Zoe: "The team tested one exposure. That can establish a result under that condition, but it cannot show the whole pattern across lower and higher exposures." Which response belongs in the gap?

- A. Correct. We do not yet have an exposure-response relationship. Keep that limitation beside the result so the development discussion does not assume a series that was never performed.
- B. Ask for the relevant study report section and any supporting record. We should correct the summary from verified information, not fill the gap with the most favorable wording.
- C. We need the appropriate uncertainty interval or other specified analysis and the underlying results. A percentage by itself does not establish statistical significance or the reliability of the estimate.
- D. The pharmacokinetics information addresses the disposition and exposure over time. The biological effect belongs to the pharmacodynamic question; neither can be replaced by a vague statement that the dose worked.

Review 3 / Meaning and context / continued

4. Rebuild the exchange from "A confidentiality agreement is not a material license".
Julia: "Then our own patentability work and a third-party-rights review should not be presented as the same assessment. They answer different questions for the collaboration." **Ravi:** [missing response] **Julia:** "I will hold shipment and send the exact assessment list and laboratory names for review. The teams agree on the science; the transfer terms still need resolution." **Which response belongs in the gap?**

- A.** Yes. Examine relevant third-party rights through appropriately scoped professional review. A right we hold is not a universal permission to practice every related technology or distribute every associated material.
- B.** Exactly. A nondisclosure agreement does not automatically answer every material-use question. We must examine the actual documents rather than assume the title grants whatever the project needs.
- C.** Agree a defined publication review process with the relevant purpose, timing, and consequences. Do not assume immediate unrestricted publication or an unlimited veto when neither term has been settled.
- D.** Ownership does not itself establish freedom to operate. Other rights may matter, and the review needs the actual activity, territory, and relevant circumstances before anyone makes a clearance statement.

[Answers and explanations, page 163](#)

A Read the situation

LESSON 07 / INVESTOR AND BOARD UPDATES

Connect completed work to a scientific funding criterion and explain a conditional cash-runway calculation.

Six experiments, one unfinished milestone

Program lead Daria and finance lead Miles prepare a fictional board update. Four binding experiments and two functional runs are complete. The agreed next funding criterion requires three consistent independent functional runs; the third is pending. Unrestricted cash is \$12 million and the base-case net cash burn is \$1.2 million per month. A proposed \$0.3 million follow-up budget is not yet approved or included in that base case. The board needs milestone status and a bounded decision request, not a count presented as proof.

People: Daria, Program lead; Miles, Finance lead.

Read the record

Choose one answer per question using the facts above.

1. Why is the funding criterion not yet met?

- A. Only two of the required three independent functional runs are complete.
- B. No experiments of any kind have been completed.
- C. Four binding experiments automatically count as functional runs.
- D. Cash balance alone determines the scientific result.

2. What is the simple base-case runway at unchanged net burn?

- A. One hundred months
- B. Ten months
- C. Twelve months
- D. One month

3. How should the \$0.3 million proposal be described?

- A. A guaranteed investment return
- B. Proof that the functional criterion is met
- C. Additional proposed funding, not yet approved or included in the base case
- D. Cash already spent and reflected in the base case

[Answers and explanations, page 148](#)

B Vocabulary in use

CORE TERMS

milestone criterion

The evidence or condition required to reach a defined project milestone.

specify the milestone criterion

evidence package

The organized results and supporting records used for a decision.

assemble the evidence package

scientific risk

Uncertainty about whether the underlying biological or technical premise will hold.

reduce scientific risk

critical path

The sequence of dependent tasks determining the earliest completion point.

identify the critical path

board ask

The specific decision or support requested from the board.

state the board ask

unrestricted cash

Cash available for use without the specified restrictions of restricted funds.

report unrestricted cash

readout

The reporting of results from a study or experiment.

schedule a data readout

go/no-go decision

A defined decision to continue, stop, or redirect a program.

support a go/no-go decision

execution risk

Uncertainty about delivering the planned work as intended.

manage execution risk

dependency

An input or task that another activity relies on.

make dependencies explicit

resource allocation

Assignment of money, people, or capacity to defined work.

justify resource allocation

net cash burn

Net cash outflow over a stated period.

calculate monthly net cash burn

Say it in context

Stress the highlighted expression. Keep the surrounding words connected; pause at the end of the phrase.

milestone criterion MILESTONE CRITERION

specify the milestone criterion

Keep the meaning precise: The evidence or condition required to reach a defined project milestone.

execution risk EXECUTION RISK

manage execution risk

Keep the meaning precise: Uncertainty about delivering the planned work as intended.

B Precision and professional shorthand

EXTEND YOUR RANGE

gross cash burn

Total cash outflow before offsetting inflows over a stated period.

distinguish gross cash burn

run rate

A current rate projected over another period under stated assumptions.

qualify the run-rate estimate

downside case

A planning scenario with less favorable specified assumptions.

test the downside case

contingent funding

Funding dependent on specified future conditions.

identify contingent funding

dilution

Reduction in an existing owner's proportional interest following additional equity issuance.

explain potential dilution

milestone payment

A payment triggered by a specified achievement under an agreement.

verify milestone-payment conditions

cash runway

The estimated period before available cash is exhausted under stated assumptions.

estimate cash runway

base case

The central planning scenario used for comparison.

update the base case

budget variance

The difference between planned and actual spending on the same basis.

explain a budget variance

financing round

A defined transaction or process to raise capital.

prepare for a financing round

inflection point

A development event expected to materially change a program's position or perceived value.

define the proposed inflection point

decision record

A record of the decision, basis, conditions, and responsible parties.

maintain a decision record

Say it in context

Stress the highlighted expression. Keep the surrounding words connected; pause at the end of the phrase.

net cash burn NET CASH BURN

calculate monthly net cash burn

Keep the meaning precise: Net cash outflow over a stated period.

downside case DOWNSIDE CASE

test the downside case

Keep the meaning precise: A planning scenario with less favorable specified assumptions.

Phrases that move the work forward

Lead with the decision

We are asking for a bounded follow-up budget, not declaring the milestone complete.

Name the criterion

The gate requires three consistent independent functional runs.

Separate evidence types

Binding data support the program but do not replace the functional criterion.

Connect the spend

The proposed budget supports the next defined evidence question.

Show the runway basis

At unchanged net burn, twelve divided by one point two gives ten months.

Separate cash and science

Available cash does not establish a successful scientific result.

Use a downside case

Show what changes if the result or timing is less favorable.

Record the conditions

Capture the board's actual decision and any conditions.

Report the work

Four binding experiments and two functional runs are complete.

State the gap

The third functional run is pending.

Avoid total de-risking

One uncertainty may be reduced while other risks remain.

State approval status

The additional \$0.3 million has not yet been approved.

Keep the model current

The new proposal is outside the current base case.

Name the dependency

The funding decision depends on the evidence criterion, not only the calendar.

Avoid a funding promise

A planned financing round is not cash already received.

Close with the next readout

Return with the third-run result and the updated cash implications.

Precision in real exchanges

Purpose: State the gap

Useful wording: The third functional run is pending.

Purpose: Separate evidence types

Useful wording: Binding data support the program but do not replace the functional criterion.

D Choose the response that fits

Choose one response for each situation. Preserve the facts, the decision boundary, and the purpose of the exchange.

1. Which opening is most decision-ready?

- A.** Two functional runs are complete; the third required by the funding criterion is pending, and we request \$0.3 million for the defined follow-up.
- B.** Six experiments prove the milestone is met.
- C.** The program is completely de-risked because the slide is finished.
- D.** The cash balance guarantees a positive third result.

2. What makes the ten-month runway conditional?

- A.** It proves future funding will arrive.
- B.** It includes every unapproved future cost automatically.
- C.** It depends only on the number of experiments completed.
- D.** It assumes unchanged net burn and the stated available cash basis.

3. A colleague needs the term for this meaning: A defined decision to continue, stop, or redirect a program. Which term fits?

- A.** run rate
- B.** dilution
- C.** go/no-go decision
- D.** board ask

D Choose the response that fits / continued

4. Rebuild the exchange from "Six experiments, one unfinished milestone". Daria: "We also need to revise the phrase fully de-risked. The completed work may reduce some uncertainty, but the pending functional result could still affect the direction." Miles: [missing response] Daria: "My request is the additional three-hundred-thousand-dollar budget for the defined follow-up. I am not asking for an unlimited commitment to every later development stage." Which response belongs in the gap?

- A.** Identify that dependency explicitly. The calendar alone does not satisfy an evidence gate, and a completed run still needs its result evaluated against the criterion.
- B.** State the milestone criterion before the count. The agreed requirement is three consistent independent functional runs, and we currently have two with the third still pending.
- C.** Exactly. The evidence package should separate those categories. The board needs to see which result addresses which criterion, not infer progress from a single large total.
- D.** Name the remaining scientific risk. Do not turn progress into a claim that every uncertainty has disappeared, particularly when the agreed evidence condition remains open.

[Answers and explanations, page 148](#)

One useful distinction

Six completed experiments do not satisfy a criterion requiring three consistent independent functional runs when only two are complete. The category and quality of evidence matter. A milestone is not met merely because the activity count looks substantial.

E Conversation

Six experiments, one unfinished milestone

Six experiments, one unfinished milestone

Complete the numbered gaps. Use each bank entry once; some entries contain several words.

WORD AND PHRASE BANK

base case / contingent funding / board ask / cash runway / decision record /
scientific risk / downside case / dependency / milestone criterion / evidence package

- 01 **Daria:** The update opens with six experiments completed. That is accurate as an activity count, but I am concerned it makes the next funding milestone sound finished.
- 02 **Miles:** State the ¹ _____ before the count. The agreed requirement is three consistent independent functional runs, and we currently have two with the third still pending.
- 03 **Daria:** Four of the six completed experiments are binding work. They support the program, but they do not replace the particular functional evidence required at this gate.
- 04 **Miles:** Exactly. The ² _____ should separate those categories. The board needs to see which result addresses which criterion, not infer progress from a single large total.
- 05 **Daria:** We also need to revise the phrase fully de-risked. The completed work may reduce some uncertainty, but the pending functional result could still affect the direction.
- 06 **Miles:** Name the remaining ³ _____. Do not turn progress into a claim that every uncertainty has disappeared, particularly when the agreed evidence condition remains open.

E Conversation / continued

- 07 **Daria:** My request is the additional three-hundred-thousand-dollar budget for the defined follow-up. I am not asking for an unlimited commitment to every later development stage.
- 08 **Miles:** Make that the ⁴ _____. State the work it supports and its approval status. At present the amount is proposed, not approved or already incorporated into the base case.
- 09 **Daria:** The finance panel shows twelve million dollars of unrestricted cash and net burn of one point two million a month. That gives ten months under unchanged assumptions.
- 10 **Miles:** Yes, as a simple ⁵ _____ illustration. Put the assumptions next to the number so it is not heard as a guarantee that every future spending plan is already covered.

Conversation continues on the next page.

Six experiments, one unfinished milestone

CONVERSATION / CONTINUED

- 11 **Daria:** Show the proposed three hundred thousand separately. What happens to the forecast if the board approves it, given that the base case excludes it?
- 12 **Miles:** Update the ⁶ _____ if the board approves new spending, using the actual timing assumptions. Approval changes the plan; it does not make the original calculation timeless.
- 13 **Daria:** There is also a proposed financing round later. We should keep that distinct from cash already available rather than use it to make the runway look longer today.
- 14 **Miles:** Correct. Treat any ⁷ _____ according to its actual status. A plan to raise money is not a receipt, and an unmet scientific condition should remain visible.
- 15 **Daria:** For the schedule, the third functional run is the key unresolved item. The board should understand how its outcome connects to the next program decision.
- 16 **Miles:** Identify that ⁸ _____ explicitly. The calendar alone does not satisfy an evidence gate, and a completed run still needs its result evaluated against the criterion.
- 17 **Daria:** We can also show what happens if the result does not support continuation or if the timing moves. That makes the spending choice more concrete.
- 18 **Miles:** Use a stated ⁹ _____ without presenting it as a prediction. The purpose is to show which assumptions change the resource choice and when the board would revisit it.
- 19 **Daria:** I will put the third functional run and the budget request on the decision slide. Please add when the board will see the result and updated cash position.
- 20 **Miles:** Capture the actual approval or deferral in the ¹⁰ _____. Keep funding authorization, experiment completion, and a successful scientific result distinct, even on the same slide.

CHECK THE GAPS

1. milestone criterion / 2. evidence package / 3. scientific risk / 4. board ask / 5. cash runway / 6. base case / 7. contingent funding / 8. dependency / 9. downside case / 10. decision record

[Why these answers fit, page 150](#)

F Check accuracy and scope

Six experiments, one unfinished milestone

Return to the case

Program lead Daria and finance lead Miles prepare a fictional board update. Four binding experiments and two functional runs are complete. The agreed next funding criterion requires three consistent independent functional runs; the third is pending. Unrestricted cash is \$12 million and the base-case net cash burn is \$1.2 million per month. A proposed \$0.3 million follow-up budget is not yet approved or included in that base case. The board needs milestone status and a bounded decision request, not a count presented as proof.

Choose one answer per question. Use the case facts and keep any uncertainty or limits intact.

1. The board packet counts six completed experiments against the three-run gate. What is the reporting error?

- A. It treats the two functional runs as pending even though they are complete.
- B. It excludes a third completed functional run that is already in the record.
- C. It combines different evidence categories although the criterion specifies functional runs.
- D. It understates the completed activity because six is fewer than three.

2. What should happen if the new budget is approved?

- A. Keep calling it excluded from every forecast permanently.
- B. Treat approval as proof of scientific success.
- C. Add the budget amount to cash as though it were revenue.
- D. Update the cash model for the actual spending assumptions and record the decision.

[Answers and explanations, page 151](#)

Listen for the distinction

Swap roles. State ten months at the base-case burn and the unapproved \$0.3 million outside that model.

A board update should connect evidence and choice

Senior audiences often ask whether a program is de-risked. Identify which uncertainty has been reduced and which criterion remains open. A clear request names the proposed work and resources without presenting a favorable experimental outcome or future funding as guaranteed.

F Say it / transfer to a new case

New spending changes the assumptions

A fictional program has \$9 million of available cash and a steady net burn of \$1.5 million per month. A new project cost is proposed but excluded from that base case.

Complete the four gaps. With a partner, read alternate roles, then switch. Studying alone, read both roles and pause before each response.

WORD AND PHRASE BANK

model / excluded / six / burn

- 01 **Finance lead:** The simple base-case runway is ¹ _____ months.
- 02 **Program lead:** That assumes an unchanged net ² _____.
- 03 **Finance lead:** The new project cost is currently ³ _____.
- 04 **Program lead:** Approval would require an updated cash ⁴ _____.

CHECK THE GAPS

1. six / 2. burn / 3. excluded / 4. model

[Why these answers fit, page 151](#)

Rebuild the exchange

Choose the missing response. Read the completed three-turn exchange aloud, changing roles on the second reading.

1. Rebuild the exchange from "Six experiments, one unfinished milestone". Daria: "There is also a proposed financing round later. We should keep that distinct from cash already available rather than use it to make the runway look longer today." Miles: [missing response] Daria: "For the schedule, the third functional run is the key unresolved item. The board should understand how its outcome connects to the next program decision." Which response belongs in the gap?

- A.** State the milestone criterion before the count. The agreed requirement is three consistent independent functional runs, and we currently have two with the third still pending.
- B.** Exactly. The evidence package should separate those categories. The board needs to see which result addresses which criterion, not infer progress from a single large total.
- C.** Correct. Treat any contingent funding according to its actual status. A plan to raise money is not a receipt, and an unmet scientific condition should remain visible.
- D.** Update the base case if the board approves new spending, using the actual timing assumptions. Approval changes the plan; it does not make the original calculation timeless.

[Answers and explanations, page 152](#)

A Read the situation

LESSON 08 / PARTNERING AND BUSINESS DEVELOPMENT

Clarify the scope and conditions of a proposed partnership without confusing a discussion, an option, and a granted license.

Define the collaboration before granting exclusivity

Biotech partnering lead Nina meets prospective partner Tomas. The proposed first stage is a six-month nonclinical evaluation of two fictional targets, T2 and T5. Tomas requests worldwide exclusive rights across all platform applications before the collaboration scope is defined. No license, option, budget, or governance terms are approved. Nina is authorized to discuss a narrower proposal, not grant rights. They must identify the scope, evidence, decision process, and unresolved commercial terms for a reviewed term sheet.

People: Nina, Biotech partnering lead; Tomas, Prospective partner.

Read the record

Choose one answer per question using the facts above.

1. What is the proposed first-stage work?

- A. An approved clinical trial across all diseases
- B. Permanent assignment of the whole platform
- C. A six-month nonclinical evaluation of T2 and T5
- D. Worldwide commercial development of every application

2. What authority does Nina have?

- A. Discuss a narrower proposal, not grant rights
- B. Execute every exclusive license immediately
- C. Approve all governance and budget terms
- D. Assign unrelated third-party patents

3. What remains unapproved?

- A. The identity of the two proposed targets
- B. The proposed six-month evaluation duration
- C. License, option, budget, and governance terms
- D. The fact that Tomas requested exclusivity

[Answers and explanations, page 153](#)

B Vocabulary in use

CORE TERMS

partnering thesis

The argument for why a collaboration could create value for both parties.

articulate the partnering thesis

evaluation license

Permission limited to a defined assessment purpose under agreed terms.

scope an evaluation license

option exercise

The act of using an option according to its agreed conditions.

define option-exercise requirements

exclusivity scope

The defined activities, rights, territory, and period covered by exclusivity.

narrow the exclusivity scope

territorial restriction

A geographic limit on the relevant rights or activities.

clarify territorial restrictions

sublicensing

Granting another party rights under authority provided by a license.

address sublicensing permission

strategic fit

Alignment between the collaboration and the parties' capabilities or goals.

assess strategic fit

option agreement

An agreement giving a defined opportunity to obtain specified rights on stated conditions.

negotiate an option agreement

license grant

The clause or act conveying specified permission under a license.

delimit the license grant

field restriction

A limitation to specified applications or uses.

define a field restriction

reserved rights

Rights explicitly retained rather than granted to the other party.

identify reserved rights

diligence obligation

An agreed requirement to make specified efforts or progress.

negotiate diligence obligations

Say it in context

Stress the highlighted expression. Keep the surrounding words connected; pause at the end of the phrase.

partnering thesis PARTNERING THESIS

articulate the partnering thesis

Keep the meaning precise: The argument for why a collaboration could create value for both parties.

license grant LICENSE GRANT

delimit the license grant

Keep the meaning precise: The clause or act conveying specified permission under a license.

B Precision and professional shorthand

EXTEND YOUR RANGE

development milestone

A defined development achievement linked to review or agreed consequences.

specify development milestones

royalty

A payment calculated on an agreed basis for use of licensed rights.

define the royalty basis

cost sharing

Allocation of specified expenses between collaborating parties.

agree cost sharing

governance

The agreed structures and rules for overseeing a collaboration.

define collaboration governance

termination right

A contractual ability to end an arrangement under defined conditions.

review termination rights

upfront payment

Consideration due at an initial agreed point in a transaction.

distinguish an upfront payment

milestone consideration

Payment or value contingent on a specified contractual achievement.

clarify milestone consideration

joint steering committee

A joint body with defined oversight or coordination responsibilities.

establish a joint steering committee

decision right

Authority to make a specified decision.

allocate decision rights

rights reversion

Return or cessation of specified granted rights under agreed conditions.

define rights reversion

B Precision and professional shorthand / continued

data room

An organized controlled-access collection of information for review.

maintain the data room

term sheet

A document summarizing proposed principal deal terms, with legal effect depending on its wording.

prepare a reviewed term sheet

Say it in context

Stress the highlighted expression. Keep the surrounding words connected; pause at the end of the phrase.

diligence obligation DILIGENCE OBLIGATION

negotiate diligence obligations

Keep the meaning precise: An agreed requirement to make specified efforts or progress.

cost sharing COST SHARING

agree cost sharing

Keep the meaning precise: Allocation of specified expenses between collaborating parties.

Phrases that move the work forward

Acknowledge the interest

I understand that you want protection for the resources you would commit.

Challenge the breadth

All platform applications is broader than the work currently proposed.

Ask about the field

Which specific applications need exclusivity for the evaluation?

Protect retained uses

We need to identify the rights and activities each party retains.

Define the trigger

Which evidence and conditions would permit an option to be exercised?

Clarify funding

Which costs would each party bear during the evaluation?

Avoid assumed agreement

Those terms are still open and subject to the required review.

Check the document

Identify which term-sheet provisions, if any, are intended to bind the parties.

Define the first stage

The proposed evaluation covers T2 and T5 for six months.

Separate discussion from grant

I can discuss scope, but I cannot grant rights in this meeting.

Clarify duration

What period would the proposed restriction cover?

Distinguish the option

A future licensing option is not the same as a present commercial license.

Connect commitment

Any exclusivity proposal needs appropriately defined obligations and review.

Ask about governance

Who would have authority over scope, budget, and continuation decisions?

Limit the information

Provide data-room access within the agreed confidentiality and use conditions.

Close the meeting

We will prepare a narrower proposal without representing that rights are already granted.

Precision in real exchanges

Purpose: Separate discussion from grant

Useful wording: I can discuss scope, but I cannot grant rights in this meeting.

Purpose: Ask about the field

Useful wording: Which specific applications need exclusivity for the evaluation?

D Choose the response that fits

Choose one response for each situation. Preserve the facts, the decision boundary, and the purpose of the exchange.

1. Which counterproposal fits Nina's authority?

- A.** Assign every future invention without review.
- B.** Treat the request as an executed license.
- C.** Prepare a reviewed proposal limited to the two-target, six-month evaluation and explicitly unresolved terms.
- D.** Grant worldwide exclusive rights to all platform applications immediately.

2. Why distinguish an option from a license?

- A.** An option removes the need to define any conditions.
- B.** An option concerns a defined opportunity to obtain rights, while a license grants specified permission.
- C.** Every option already grants all commercial rights.
- D.** A license is always merely a meeting invitation.

3. A colleague needs the term for this meaning: An agreement giving a defined opportunity to obtain specified rights on stated conditions. Which term fits?

- A.** termination right
- B.** option agreement
- C.** royalty
- D.** territorial restriction

D Choose the response that fits / continued

4. Rebuild the exchange from "Define the collaboration before granting exclusivity".
Tomas: "Could we start with evaluation rights and secure a route to a later commercial license if the results meet agreed criteria?" Nina: [missing response]
Tomas: "We would need to know what evidence qualifies and when we must decide. Otherwise the option could be too uncertain to support a meaningful investment." Which response belongs in the gap?

- A.** A defined field restriction could keep the first stage aligned with the actual work. Broader applications require their own review; I cannot grant platform-wide rights in this meeting.
- B.** Yes, specify cost sharing for the actual work. A broad expression of interest should not conceal who is paying for which activities or approving additional spending.
- C.** A joint steering committee can help if its authority is defined. We still need to assign decisions about scope, budget, continuation, and matters reserved for authorized signatories.
- D.** We can discuss an option agreement as a proposal. It would need clear scope, conditions, and approval; a possible future option is not already a commercial license.

[Answers and explanations, page 153](#)

One useful distinction

A proposal to discuss exclusivity does not grant it. A term sheet is not automatically entirely nonbinding; its effect depends on the actual wording and law. An option to obtain rights is also distinct from an exercised option or an existing license grant.

E Conversation

Define the collaboration before granting exclusivity

Define the collaboration before granting exclusivity

Complete the numbered gaps. Use each bank entry once; some entries contain several words.

WORD AND PHRASE BANK

term sheet / diligence obligation / reserved rights / rights reversion / exclusivity scope / option agreement / field restriction / joint steering committee / cost sharing / option exercise

- 01 **Tomas:** Before we commit resources, we would like worldwide exclusive rights across the platform. We do not want to fund the work while a competitor receives the same opportunity.
- 02 **Nina:** I understand the concern, but the ¹ _____ you describe is wider than the proposed six-month evaluation of T2 and T5. Let us identify the activity you need protected.
- 03 **Tomas:** Our immediate interest is those two targets. We also see possible applications beyond them, and we would prefer not to renegotiate every time the opportunity develops.
- 04 **Nina:** A defined ² _____ could keep the first stage aligned with the actual work. Broader applications require their own review; I cannot grant platform-wide rights in this meeting.
- 05 **Tomas:** Could we start with evaluation rights and secure a route to a later commercial license if the results meet agreed criteria?
- 06 **Nina:** We can discuss an ³ _____ as a proposal. It would need clear scope, conditions, and approval; a possible future option is not already a commercial license.

E Conversation / continued

- 07 **Tomas:** We would need to know what evidence qualifies and when we must decide. Otherwise the option could be too uncertain to support a meaningful investment.
- 08 **Nina:** Define the ⁴ _____ requirements alongside the evidence criteria. We should also distinguish scientific success from the separate commercial and legal conditions for obtaining rights.
- 09 **Tomas:** What happens to your own research during the evaluation? We do not necessarily need to stop unrelated platform work, but we need to understand competing activity.
- 10 **Nina:** Identify the ⁵ _____ and proposed restrictions explicitly. Neither side should infer a platform-wide freeze from a limited evaluation, nor assume an exception that the terms do not state.

Conversation continues on the next page.

Define the collaboration before granting exclusivity

CONVERSATION / CONTINUED

- 11 **Tomas:** We can bring specialist capability and funding for the evaluation, but the division of costs has not been discussed. That needs to be part of the same proposal.
- 12 **Nina:** Yes, specify ⁶ _____ for the actual work. A broad expression of interest should not conceal who is paying for which activities or approving additional spending.
- 13 **Tomas:** If we seek some exclusivity, you will want assurance that the work moves forward. We should discuss what commitments would accompany that protection.
- 14 **Nina:** Appropriate ⁷ _____ terms can address that, subject to review. The proposal should state the expected progress and consequences rather than rely on a general promise to try.
- 15 **Tomas:** Could a joint committee handle routine technical decisions? I do not want a small adjustment to require another executive negotiation every time.
- 16 **Nina:** A ⁸ _____ can help if its authority is defined. We still need to assign decisions about scope, budget, continuation, and matters reserved for authorized signatories.
- 17 **Tomas:** We should also describe what happens if the evaluation ends without a later license. Materials, data access, and any temporary restrictions need a clear position.
- 18 **Nina:** Address ⁹ _____ and the relevant end-of-project obligations in the reviewed proposal. Do not assume that a temporary arrangement continues indefinitely because nobody discussed its end.
- 19 **Tomas:** I will tell our team we are preparing a two-target proposal, not announcing worldwide exclusivity. Send me the open points so we can assign reviewers on our side.
- 20 **Nina:** Exactly. We will prepare a ¹⁰ _____ covering the two-target evaluation and open issues, with its intended legal effect reviewed. No license, option, or exclusivity grant is approved by this discussion alone.

CHECK THE GAPS

1. exclusivity scope / 2. field restriction / 3. option agreement / 4. option exercise / 5. reserved rights / 6. cost sharing / 7. diligence obligation / 8. joint steering committee / 9. rights reversion / 10. term sheet

[Why these answers fit, page 154](#)

F Check accuracy and scope

Define the collaboration before granting exclusivity

Return to the case

Biotech partnering lead Nina meets prospective partner Tomas. The proposed first stage is a six-month nonclinical evaluation of two fictional targets, T2 and T5. Tomas requests worldwide exclusive rights across all platform applications before the collaboration scope is defined. No license, option, budget, or governance terms are approved. Nina is authorized to discuss a narrower proposal, not grant rights. They must identify the scope, evidence, decision process, and unresolved commercial terms for a reviewed term sheet.

Choose one answer per question. Use the case facts and keep any uncertainty or limits intact.

1. A draft names a joint steering committee but gives it no powers. Which question addresses that gap?

- A. Which targets are included in the six-month evaluation?
- B. Which territories would the proposed exclusive rights cover?
- C. Which material will be placed in the controlled data room?
- D. Who may approve scope changes, budgets, and continuation decisions?

2. What should the meeting record say?

- A. The unapproved budget has already been paid.
- B. The parties will prepare a narrower proposal; no rights grant is approved.
- C. Worldwide exclusivity is effective because Tomas requested it.
- D. Every term-sheet provision is automatically nonbinding.

[Answers and explanations, page 156](#)

Listen for the distinction

Swap roles. Separate a possible option, its future exercise, and a current license; keep the terms unapproved.

Explore interests before accepting the broad wording

A request for exclusivity may reflect a concern about investing resources while a competitor receives the same opportunity. Acknowledge that concern, then clarify the protected activity and duration. A narrower proposal can keep negotiation moving without implying that rights have already been granted.

F Say it / transfer to a new case

An option is not an exercised grant

Two partners discuss a possible option to negotiate a future license after a defined evaluation. No option is signed and no license is granted. A meeting note says commercial rights acquired.

Complete the four gaps. With a partner, read alternate roles, then switch. Studying alone, read both roles and pause before each response.

WORD AND PHRASE BANK

granted / signed / discussion / status

- 01 **Partner:** The possible option is still under ¹ _____.
- 02 **Lead:** No option has been ² _____.
- 03 **Partner:** No commercial license has been ³ _____.
- 04 **Lead:** The meeting note must preserve that ⁴ _____.

CHECK THE GAPS

1. discussion / 2. signed / 3. granted / 4. status

[Why these answers fit, page 156](#)

Rebuild the exchange

Choose the missing response. Read the completed three-turn exchange aloud, changing roles on the second reading.

1. Rebuild the exchange from "Define the collaboration before granting exclusivity".

Tomas: "If we seek some exclusivity, you will want assurance that the work moves forward. We should discuss what commitments would accompany that protection." **Nina:** [missing response] **Tomas:** "Could a joint committee handle routine technical decisions? I do not want a small adjustment to require another executive negotiation every time." Which response belongs in the gap?

- A.** A defined field restriction could keep the first stage aligned with the actual work. Broader applications require their own review; I cannot grant platform-wide rights in this meeting.
- B.** I understand the concern, but the exclusivity scope you describe is wider than the proposed six-month evaluation of T2 and T5. Let us identify the activity you need protected.
- C.** Appropriate diligence obligation terms can address that, subject to review. The proposal should state the expected progress and consequences rather than rely on a general promise to try.
- D.** We can discuss an option agreement as a proposal. It would need clear scope, conditions, and approval; a possible future option is not already a commercial license.

[Answers and explanations, page 157](#)

Review 4 / Meaning and context

Use language from the lessons you have completed. Choose one answer per question.

Case file

Revisit "Investor and Board Updates" and "Partnering and Business Development". Choose precise terminology, then reconstruct the missing responses using both neighboring turns. The final two questions also revisit earlier conversations.

1. A colleague needs the term for this meaning: The organized results and supporting records used for a decision. Which term fits?

- A. dependency
- B. cash runway
- C. evidence package
- D. financing round

2. A colleague needs the term for this meaning: A limitation to specified applications or uses. Which term fits?

- A. partnering thesis
- B. field restriction
- C. development milestone
- D. governance

3. Rebuild the exchange from "A confidentiality agreement is not a material license".
Julia: "If a new invention results, naming the people who contributed is not necessarily the same as deciding which organization will own the resulting rights."
Ravi: [missing response] Julia: "The recipient wants to publish. Can the draft specify how review would work, including timing, without implying either immediate unrestricted publication or an unlimited veto?" Which response belongs in the gap?

- A. Define the permitted use precisely and address any onward transfer. The scientific plan should match the scope being reviewed, including which organizations would actually handle the material.
- B. Exactly. A nondisclosure agreement does not automatically answer every material-use question. We must examine the actual documents rather than assume the title grants whatever the project needs.
- C. Clarify any know-how being supplied and the authorized uses. Physical possession of a reference protein does not automatically settle rights in every method discussed alongside it.
- D. Correct. Inventorship and ownership are different legal questions. We should not resolve either casually in an email saying that every new idea belongs to the team.

Review 4 / Meaning and context / continued

4. Rebuild the exchange from "Define the collaboration before granting exclusivity".
Tomas: "We should also describe what happens if the evaluation ends without a later license. Materials, data access, and any temporary restrictions need a clear position." Nina: [missing response] Tomas: "I will tell our team we are preparing a two-target proposal, not announcing worldwide exclusivity. Send me the open points so we can assign reviewers on our side." Which response belongs in the gap?

- A.** Yes, specify cost sharing for the actual work. A broad expression of interest should not conceal who is paying for which activities or approving additional spending.
- B.** We can discuss an option agreement as a proposal. It would need clear scope, conditions, and approval; a possible future option is not already a commercial license.
- C.** Define the option exercise requirements alongside the evidence criteria. We should also distinguish scientific success from the separate commercial and legal conditions for obtaining rights.
- D.** Address rights reversion and the relevant end-of-project obligations in the reviewed proposal. Do not assume that a temporary arrangement continues indefinitely because nobody discussed its end.

[Answers and explanations, page 166](#)

Language for the next case

A familiar cell-line label is not an identity check

cell-line authentication

Cell-line authentication establishes identity through appropriate evidence; a matching label alone is not an identity check.

Inez: Not on the label alone. We need the cell-line authentication records and a clear link to the material we actually received.

passage history

Passage history records the sequence of cell subculturing and relevant lineage information; inconsistent counting needs clarification.

Inez: Reconcile the passage history. Do not assume two identical numbers describe equivalent histories or that different numbers necessarily prove a problem.

cross-contamination

Cross-contamination introduces material from another source and may not be excluded by normal-looking morphology alone.

Inez: No. Appearance may be an observation, but it does not rule out misidentification or cross-contamination.

mycoplasma testing

Mycoplasma testing checks for a particular contamination concern; it is not interchangeable with establishing the cell line's identity.

Caleb: Then identity testing and mycoplasma testing answer different questions, even when both appear in the quality package.

working cell bank

A working cell bank supplies routine work from a defined cell-bank lineage; its relationship to the source bank must remain traceable.

Inez: The working cell bank should have a traceable relationship to the source bank under our system.

provenance

Provenance identifies the material's origin and history; relabeling without resolving the discrepancy would hide that information.

Inez: Good. Preserve the provenance and record any authorized correction with its basis.

Read the phrases aloud. Then complete the conversation on the following pages using the word bank.

Conversation

A familiar cell-line label is not an identity check

A research team wants to compare a newly received human cell stock with its existing working stock. Labels look similar, but the identity records and passage history have not been reconciled. A negative mycoplasma result is available only for the existing stock. This discussion concerns research readiness, not a laboratory protocol.

Complete the numbered gaps. Use each bank entry once; some entries contain several words.

WORD AND PHRASE BANK

cell-line authentication / working cell bank / passage history / cross-contamination /
provenance / mycoplasma testing

- 01 **Caleb:** The new stock has the same cell-line name as ours. Can we combine its results with the current study?
- 02 **Inez:** Not on the label alone. We need the ¹ _____ records and a clear link to the material we actually received.
- 03 **Caleb:** Our current stock tested negative for mycoplasma. I assumed that covered the comparison.
- 04 **Inez:** That result concerns the tested stock and sampling point. It does not establish the new stock's identity or contamination status.
- 05 **Caleb:** Then identity testing and ² _____ answer different questions, even when both appear in the quality package.
- 06 **Inez:** Exactly. We need the relevant results, methods, dates, and material identifiers, with their limits intact.

Conversation / continued

- 07 **Caleb:** The old stock's label also has a passage number. The incoming paperwork lists a different number without explaining the counting convention.
- 08 **Inez:** Reconcile the ³ _____. Do not assume two identical numbers describe equivalent histories or that different numbers necessarily prove a problem.
- 09 **Caleb:** The supplier refers to a master bank, while our experiments use a working bank. Can you explain the relationship in the project summary?
- 10 **Inez:** The ⁴ _____ should have a traceable relationship to the source bank under our system.

Conversation continues on the next page.

A familiar cell-line label is not an identity check

CONVERSATION / CONTINUED

- 11 **Caleb:** Could normal-looking cells be enough reassurance while we wait for the records?
- 12 **Inez:** No. Appearance may be an observation, but it does not rule out misidentification or
5 _____.
- 13 **Caleb:** We have not used the incoming stock yet. Should I tell the team the comparison is awaiting the readiness review?
- 14 **Inez:** Yes. Follow the site's handling and status controls, and keep the two stocks and their records distinct while the questions are resolved.
- 15 **Caleb:** I will request the missing information rather than rewrite the incoming label to match our familiar name.
- 16 **Inez:** Good. Preserve the ⁶ _____ and record any authorized correction with its basis.
- 17 **Caleb:** Once the records are reconciled, we still need to decide whether pooling the datasets answers the study question.
- 18 **Inez:** Correct. Confirmed identity does not by itself establish that all experimental conditions are comparable.
- 19 **Caleb:** I will separate the material-readiness question from the data-combination decision in the update.
- 20 **Inez:** That gives the team two clear checks instead of one reassuring but unsupported statement that the stocks are the same.

CHECK THE GAPS

1. cell-line authentication / 2. mycoplasma testing / 3. passage history / 4. working cell bank / 5. cross-contamination / 6. provenance

[Why these answers fit, page 169](#)

A result from the old stock is attached to the new one

A spreadsheet links an existing stock's contamination-test result to a newly received stock. The new stock has not been assessed.

Complete the exchange using each phrase once. Read both roles, then switch roles and repeat with the bank covered.

WORD AND PHRASE BANK

stock / history / unestablished / questions

- 01 **Scientist:** This result belongs to the previously tested ¹ _____.
- 02 **Reviewer:** Restore the correct link and retain the correction ² _____.
- 03 **Scientist:** Mark the new stock's test status as ³ _____.
- 04 **Reviewer:** Keep identity and contamination as separate review ⁴ _____.

CHECK THE GAPS

1. stock / 2. history / 3. unestablished / 4. questions

[Why these answers fit, page 169](#)

Keep the distinction audible

Discuss cell-bank identity and contamination status without overstating what a test establishes.

Language for the next case

The sequencing batches also separate every study group

batch effect

A batch effect is systematic variation associated with processing groups rather than necessarily the biology under study.

Ruth: Not yet. The groups also separate by processing batch, so a batch effect could contribute to the pattern.

technical replicates

Technical replicates repeat measurement of the same biological material; they do not create additional independent biological samples.

Ruth: That would add technical replicates, depending on what is repeated. It would not create new independent biological samples by itself.

balanced design

A balanced design distributes relevant biological groups across processing conditions so those factors are not automatically identical.

Ruth: We should review a balanced design and the relevant constraints before generating more data.

confounding

Confounding means the biological group and processing batch vary together, preventing their separate effects from being identified from this design alone.

Ruth: Here we have complete confounding between group and batch. An adjustment cannot create the missing independent comparison.

Biological replicates

Biological replicates are independent biological samples that capture relevant biological variation rather than repeated readings of one sample.

Ruth: Yes. Biological replicates provide a different kind of information. The sample structure must stay visible in the analysis.

sample metadata

Sample metadata describe origin, grouping, processing, and other relevant characteristics needed to understand the analysis design.

Ruth: Correct. The sample metadata must link reliably to the expression data, including any changes or exclusions.

Read the phrases aloud. Then complete the conversation on the following pages using the word bank.

Conversation

The sequencing batches also separate every study group

A fictional RNA-sequencing study placed every case sample in batch A and every control sample in batch B. The expression plot separates the groups. No batch-independent confirmation exists. The analyst and study scientist are discussing the interpretation and a possible follow-up design, not a validated diagnostic test.

Complete the numbered gaps. Use each bank entry once; some entries contain several words.

WORD AND PHRASE BANK

confounding / balanced design / Biological replicates / technical replicates /
sample metadata / batch effect

- 01 **Dev:** The expression plot separates cases and controls cleanly. Can we call this a disease signature in the report?
- 02 **Ruth:** Not yet. The groups also separate by processing batch, so a ¹ _____ could contribute to the pattern.
- 03 **Dev:** Every case was in A and every control in B. I thought the analysis could simply adjust for that afterward.
- 04 **Ruth:** Here we have complete ² _____ between group and batch. An adjustment cannot create the missing independent comparison.
- 05 **Dev:** Would sequencing each sample again count as more independent evidence for the disease difference?
- 06 **Ruth:** That would add ³ _____, depending on what is repeated. It would not create new independent biological samples by itself.

Conversation / continued

- 07 **Dev:** Then we need to distinguish the number of samples from the number of times each was measured.
- 08 **Ruth:** Yes. ⁴ _____ provide a different kind of information. The sample structure must stay visible in the analysis.
- 09 **Dev:** The plot is still useful for spotting the problem, even if we cannot interpret the separation as purely biological.
- 10 **Ruth:** Exactly. Keep the plot, annotate the batch assignment, and explain the design limitation rather than hide the uncomfortable grouping.

Conversation continues on the next page.

The sequencing batches also separate every study group

CONVERSATION / CONTINUED

- 11 **Dev:** Could we remove genes that seem batch-sensitive until the case-control separation looks more convincing?
- 12 **Ruth:** Not as an outcome-driven cleanup. Filtering needs a defensible basis, and it cannot establish which part of a perfectly confounded pattern is biological.
- 13 **Dev:** For follow-up, I want the study team and analysis team to agree the assignments before sample processing begins.
- 14 **Ruth:** We should review a ⁵ _____ and the relevant constraints before generating more data.
- 15 **Dev:** We will also need enough metadata to reconstruct how every sample moved through processing.
- 16 **Ruth:** Correct. The ⁶ _____ must link reliably to the expression data, including any changes or exclusions.
- 17 **Dev:** What can we state now without implying the study is worthless?
- 18 **Ruth:** That the observed separation aligns with both disease group and batch, so this dataset alone cannot separate those explanations.
- 19 **Dev:** I will revise the headline and request review of the follow-up design. We will not present this plot as a validated disease classifier.
- 20 **Ruth:** Good. The limitation identifies what the next study needs to resolve; it does not require pretending we observed no pattern at all.

CHECK THE GAPS

1. batch effect / 2. confounding / 3. technical replicates / 4. Biological replicates / 5. balanced design / 6. sample metadata

[Why these answers fit, page 171](#)

Repeated readings are counted as new donors

Samples from five donors are each measured twice. A summary reports ten independent donors. No additional donors were recruited.

Complete the exchange using each phrase once. Read both roles, then switch roles and repeat with the bank covered.

WORD AND PHRASE BANK

readings / metadata / replicates / analysis

- 01 **Scientist:** We have five donors, not ten independent biological ¹ _____.
- 02 **Analyst:** The extra measurements provide technical repeat ² _____.
- 03 **Scientist:** Keep the donor-to-measurement links in the ³ _____.
- 04 **Analyst:** Correct the sample-size claim before interpreting the ⁴ _____.

CHECK THE GAPS

1. replicates / 2. readings / 3. metadata / 4. analysis

[Why these answers fit, page 171](#)

Keep the distinction audible

Explain confounding and challenge a confident biological interpretation of a batch-aligned result.

Language for the next case

The dataset is coded, but the proposed use has changed

Coded data

Coded data use identifiers such as study codes; coding does not by itself make every use or transfer unrestricted.

Ben: Not yet. Coded data are not automatically unrestricted. What purpose and recipients does our current authorization cover?

consent scope

Consent scope defines the relevant uses participants agreed to and any limits that must be respected in the proposed research.

Ben: Related scientifically does not settle the permission. Check the consent scope and the applicable institutional and repository conditions.

data-use agreement

A data-use agreement records permitted handling and use between parties; it must align with the governing permissions rather than replace them.

Ben: Security is necessary, but it does not authorize the purpose or recipients. We also need the appropriate data-use agreement and access decisions.

secondary-use

Secondary-use review assesses a further research purpose beyond the initially authorized use, rather than assuming access covers every question.

Ben: Then we need a secondary-use review before treating the proposal as covered.

data-use limitations

Data-use limitations specify restrictions attached to the records or consent groups; combining files does not remove those restrictions.

Ben: Map the data-use limitations before combining or transferring anything. We cannot erase differences by exporting them together.

withdrawal request

A withdrawal request requires review under the relevant consent, policy, and legal framework; its effects should not be invented or ignored.

Ben: Route that withdrawal request through the responsible team. Do not promise universal deletion or assume it has no effect.

Read the phrases aloud. Then complete the conversation on the following pages using the word bank.

Conversation

The dataset is coded, but the proposed use has changed

A team has authorized access to coded human research data for a named study. A partner proposes a different analysis and requests a copy. The new purpose, partner access, and applicable consent limitations have not been reviewed. No transfer has occurred.

Complete the numbered gaps. Use each bank entry once; some entries contain several words.

WORD AND PHRASE BANK

data-use agreement / secondary-use / data-use limitations / Coded data / consent scope
/ withdrawal request

- 01 **Farah:** The partner can run the new analysis next week. Since the files have study codes rather than names, may I send a copy?
- 02 **Ben:** Not yet. ¹ _____ are not automatically unrestricted. What purpose and recipients does our current authorization cover?
- 03 **Farah:** It names our existing study. The partner wants to investigate a different outcome using the same records.
- 04 **Ben:** Then we need a ² _____ review before treating the proposal as covered.
- 05 **Farah:** The scientific question is related. Does that make it close enough to proceed while the paperwork catches up?
- 06 **Ben:** Related scientifically does not settle the permission. Check the ³ _____ and the applicable institutional and repository conditions.
- 07 **Farah:** Some records may have different restrictions. I had planned to send one combined file for convenience.
- 08 **Ben:** Map the ⁴ _____ before combining or transferring anything. We cannot erase differences by exporting them together.
- 09 **Farah:** The partner has a secure system and experienced analysts. Would security approval be sufficient?
- 10 **Ben:** Security is necessary, but it does not authorize the purpose or recipients. We also need the appropriate ⁵ _____ and access decisions.

Conversation continues on the next page.

The dataset is coded, but the proposed use has changed

CONVERSATION / CONTINUED

- 11 **Farah:** Could I give them my login so they can inspect the fields without receiving a separate copy?
- 12 **Ben:** No. Use the approved access process with named authorized users. Sharing credentials would bypass the controls we are trying to verify.
- 13 **Farah:** I will prepare the proposed question, required fields, analysts, and planned outputs for review.
- 14 **Ben:** Include whether any new linkage is proposed and how outputs will be checked. We need the actual workflow, not just the project's title.
- 15 **Farah:** There is also a recent participant request concerning further use. I do not know how it affects copies or completed analyses.
- 16 **Ben:** Route that ⁶ _____ through the responsible team. Do not promise universal deletion or assume it has no effect.
- 17 **Farah:** For now, the partner gets no files or credentials. I can explain that the new analysis needs its own review.
- 18 **Ben:** Yes. Preserve the current access boundaries while the reviewers establish which records and uses, if any, are permitted.
- 19 **Farah:** Once the decision arrives, I will confirm the exact approved dataset and recipient list before arranging the transfer.
- 20 **Ben:** And retain the authorization with the transfer record. Scientific enthusiasm is valuable, but the permitted scope must remain traceable.

CHECK THE GAPS

1. Coded data / 2. secondary-use / 3. consent scope / 4. data-use limitations / 5. data-use agreement / 6. withdrawal request

[Why these answers fit, page 173](#)

A new collaborator requests an existing login

A collaborator is not yet an approved user of a controlled-access research dataset and asks to borrow a team member's login.

Complete the exchange using each phrase once. Read both roles, then switch roles and repeat with the bank covered.

WORD AND PHRASE BANK

process / scope / credentials / use

- 01 **Scientist:** Existing access does not authorize sharing our ¹ _____.
- 02 **Governance lead:** Submit the collaborator through the named-user access
² _____.
- 03 **Scientist:** We must also confirm that the proposed question is a permitted
³ _____.
- 04 **Governance lead:** Keep the data within the current authorized ⁴ _____
meanwhile.

CHECK THE GAPS

1. credentials / 2. process / 3. use / 4. scope

[Why these answers fit, page 173](#)

Keep the distinction audible

Clarify research-use permissions and data-sharing boundaries before a new collaboration.

01 / Answers and explanations

A / Read the situation

A1. Which evidence is supplied?

D. A 40% average reporter-signal reduction in three independent preparations of one cell line

The brief supplies a reporter result in one cell line, not cross-disease or clinical evidence.

[Return to the exercise, page 4](#)

A2. Which claim exceeds that evidence?

D. Proven activity across three diseases

The additional disease systems have not been tested in the supplied case.

[Return to the exercise, page 4](#)

A3. What is the immediate decision request?

D. Funding a bounded follow-up study

The stated request concerns a limited next research study, not a clinical or rights decision.

[Return to the exercise, page 4](#)

D / Response choices

D1. Which slide headline is best supported?

B. Reporter signal reduced by an average 40% in the tested cell line; broader applications remain untested.

The supported headline retains the observed result and its actual experimental boundary.

[Return to the exercise, page 8](#)

D2. One preparation is read three times with the same method. How should those reads be described?

D. Three technical measurements of one biological preparation

Repeated reads of the same material are technical replication. They do not create independently prepared biological units, change the measurement approach, or establish new disease applications.

[Return to the exercise, page 8](#)

01 / Answers and explanations / continued

D3. A colleague needs the term for this meaning: The biological entity a program aims to affect. Which term fits?

D. target

A Not here. disease model: An experimental system representing selected aspects of a disease. The usual combination is "qualify the disease model".

B Not here. counter-screen: A separate screen used to identify unwanted or misleading effects. The usual combination is "include a counter-screen".

C Not here. biological replicate: An independently prepared biological sample or experimental unit. The usual combination is "include biological replicates".

D Correct. target: The biological entity a program aims to affect. The usual combination is "define the target".

[Return to the exercise, page 8](#)

D4. Rebuild the exchange from "One cell line, three proposed diseases". Leo: "The slide currently turns the three preparations into a visual with three disease labels. I can see how that could imply that each disease has been tested." Nia: [missing response] Leo: "What would you say about the mechanism? The lower signal looks consistent with the proposed pathway, but the headline makes the connection sound settled." Which response belongs in the gap?

C. Keep the biological replicate description explicit. Three independent preparations tell us something about that system; they do not create evidence for three separate indications.

A Not here. This line belongs to turn 4, after Leo says: "Can we still call it a platform result? The investors need to see why this is more than a single isolated observation with no development direction." It addresses that point, not the missing turn in the supplied exchange.

B Not here. This line belongs to turn 16, after Leo says: "I will keep the forty-percent observation in the main line and put the tested system beside it. The expansion will be a proposed application, not a proven one." It addresses that point, not the missing turn in the supplied exchange.

C Correct. This is Nia's response in turn 6. It connects Leo's preceding point with Leo's follow-up. A biological replicate is an independent preparation within the tested system, not a different disease application.

D Not here. This line belongs to turn 8, after Leo says: "What would you say about the mechanism? The lower signal looks consistent with the proposed pathway, but the headline makes the connection sound settled." It addresses that point, not the missing turn in the supplied exchange.

[Return to the exercise, page 8](#)

E / Conversation

1. reporter signal

Turn 2. The reporter signal is the measured experimental output, not a direct demonstration of clinical benefit.

01 / Answers and explanations / continued

2. scientific thesis

Turn 4. The scientific thesis connects the observation to a research argument without treating every hypothesis as established.

3. biological replicate

Turn 6. A biological replicate is an independent preparation within the tested system, not a different disease application.

4. proof of mechanism

Turn 8. Proof of mechanism requires evidence for the proposed biological explanation beyond the supplied reporter observation.

5. orthogonal assay

Turn 10. An orthogonal assay uses a different measurement approach to examine the underlying biological question.

6. assay interference

Turn 12. Assay interference can alter the measured signal without establishing the intended biological effect.

7. translational hypothesis

Turn 14. A translational hypothesis proposes a link to another development setting that remains to be tested.

8. evidence gap

Turn 16. The evidence gap is the missing functional and broader-system support needed for the larger claim.

9. decision gate

Turn 18. A decision gate defines when the follow-up evidence will be reviewed against agreed continuation criteria.

10. generalizability

Turn 20. Generalizability concerns application beyond the tested setting, which the supplied evidence has not yet established.

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01 / Answers and explanations / continued

F / Accuracy and scope

F1. Why request an orthogonal functional readout?

C. To examine the biological question through a different measurement approach

A different approach can test whether the original signal reflects the intended biology.

[Return to the exercise, page 13](#)

F2. Which funding request matches the brief?

D. Support a bounded follow-up addressing functional confirmation and broader relevance.

The brief asks for a next research study that addresses the stated evidence gaps.

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F / Guided speaking

1. model

Scientist: The signal was observed in one model.

Turn 1. The supplied result belongs to one tested cell model only.

2. untested

Partner: The other two are still untested.

Turn 2. The briefing states that no testing has occurred in those additional systems.

3. hypothesis

Scientist: Broader application remains a hypothesis.

Turn 3. The proposed extension is a testable idea rather than an established result.

4. gap

Partner: The next study should address that evidence gap.

Turn 4. The missing data concern whether the finding extends beyond the tested setting.

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01 / Answers and explanations / continued

F / Rebuild the exchange

1. Rebuild the exchange from "One cell line, three proposed diseases". Leo: "How do we describe the proposed disease expansion without making it sound like a result? I want an ambitious but defensible sentence in the investor discussion." Nia: [missing response] Leo: "I will keep the forty-percent observation in the main line and put the tested system beside it. The expansion will be a proposed application, not a proven one." Which response belongs in the gap?

D. Call it a translational hypothesis and name the additional systems we propose to evaluate. The audience can understand the opportunity without being told that unperformed work has succeeded.

A Not here. This line belongs to turn 2, after Leo says: "The headline says our platform has proven activity across three diseases. It sounds strong, but I want to know whether each part of that claim is supported." It addresses that point, not the missing turn in the supplied exchange.

B Not here. This line belongs to turn 10, after Leo says: "What would the next study tell us that another reporter run would not? The funding request needs a scientific question, not just a larger sample count." It addresses that point, not the missing turn in the supplied exchange.

C Not here. This line belongs to turn 20, after Leo says: "I will remove the three-disease claim and request the bounded follow-up. Keep the forty-percent result beside the actual cell system so the claim cannot drift again." It addresses that point, not the missing turn in the supplied exchange.

D Correct. This is Nia's response in turn 14. It connects Leo's preceding point with Leo's follow-up. A translational hypothesis proposes a link to another development setting that remains to be tested.

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02 / Answers and explanations

A / Read the situation

A1. What is consistent within each run?

B. The stated coefficient of variation is 5%.

The briefing gives a five-percent within-run coefficient of variation on each day.

[Return to the exercise, page 15](#)

A2. What changes across days?

A. The mean signal: 80, 100, and 125 units

The day means differ even though the within-run variation is stated as the same.

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A3. What cannot yet be concluded?

A. A confirmed cause or full validation status

Neither a cause nor acceptance criteria sufficient for a validation decision are provided.

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D / Response choices

D1. Which statement fits the data?

B. Each run has 5% CV, while day means differ from 80 to 125 units.

The correct statement keeps within-run spread separate from the observed between-day differences.

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D2. Relative to day two's mean of 100, how much higher is day three's mean of 125?

A. 25%

The increase is twenty-five divided by the reference value one hundred, giving twenty-five percent.

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02 / Answers and explanations / continued

D3. A colleague needs the term for this meaning: Precision under specified changed conditions, commonly across laboratories. Which term fits?

B. reproducibility

A Not here. normalization: Adjusting results to a defined comparison or reference basis. The usual combination is "document normalization".

B Correct. reproducibility: Precision under specified changed conditions, commonly across laboratories. The usual combination is "define reproducibility conditions".

C Not here. mean signal: The average measured output for a defined group. The usual combination is "compare mean signals".

D Not here. quality-control sample: A sample used to monitor analytical performance. The usual combination is "review quality-control samples".

[Return to the exercise, page 19](#)

D4. Rebuild the exchange from "Tight wells, shifting days". Chen: "We intended the same nominal control level. Could the newest operator explain the shift? That was the first suggestion in yesterday's meeting." Imani: [missing response] Chen: "Right. If the operator and reagent lot changed together, the pattern would not isolate either one. I should not report an attribution we cannot defend." Which response belongs in the gap?

D. Let us compare the run metadata first: operator, reagent lot, calibration and relevant conditions. We do not yet know which changes coincide.

A Not here. This line belongs to turn 10, after Chen says: "All three runs were in this laboratory. Is between-day reproducibility the clearest heading, or would another term make the conditions more precise?" It addresses that point, not the missing turn in the supplied exchange.

B Not here. This line belongs to turn 18, after Chen says: "Then retain the original readings and show how any adjusted result was derived. The unadjusted plot should not disappear from the package." It addresses that point, not the missing turn in the supplied exchange.

C Not here. This line belongs to turn 12, after Chen says: "I also wrote that day three rose twenty percent from day two. I divided twenty-five by the final value of one hundred twenty-five." It addresses that point, not the missing turn in the supplied exchange.

D Correct. This is Imani's response in turn 6. It connects Chen's preceding point with Chen's follow-up. Run metadata identifies conditions such as operator, reagent lot, and calibration that can support investigation.

[Return to the exercise, page 19](#)

E / Conversation

1. within-run variation

Turn 2. Within-run variation describes spread inside each run, not whether the averages match across different days.

02 / Answers and explanations / continued

2. coefficient of variation

Turn 4. The coefficient of variation expresses relative spread as standard deviation divided by the mean.

3. run metadata

Turn 6. Run metadata identifies conditions such as operator, reagent lot, and calibration that can support investigation.

4. root-cause investigation

Turn 8. A root-cause investigation tests supported explanations rather than assigning responsibility from an incomplete pattern.

5. intermediate precision

Turn 10. Intermediate precision covers relevant variation within one laboratory, including between-day conditions.

6. mean signal

Turn 12. Mean signal is the average measured output being compared between day two and day three.

7. acceptance criterion

Turn 14. An acceptance criterion supplies the predefined requirement needed for a formal performance judgment.

8. normalization

Turn 16. Normalization requires a defined and justified reference basis rather than an adjustment chosen only to conceal disagreement.

9. calibration

Turn 18. Calibration records describe the relationship to reference values and may help explain measurement differences.

10. precision

Turn 20. Precision concerns agreement among repeated measurements under specified conditions and must be qualified by those conditions.

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02 / Answers and explanations / continued

F / Accuracy and scope

F1. Which follow-up best supports investigation?

A. Compare traceable run conditions and raw data before assigning a cause.

Comparing records and raw data can test explanations without prematurely choosing one.

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F2. A colleague rescales each day to a mean of 100 and calls the assay reproducible. What remains unresolved?

D. Whether the adjustment has a justified basis and the original between-day variation is understood

Equalizing the plotted means is the adjustment's result, not independent evidence of performance. The original shift and the scientific basis for normalization still require examination.

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F / Guided speaking

1. thirty

Analyst: The mean rose by thirty units.

Turn 1. Subtracting one hundred twenty from one hundred fifty gives thirty units.

2. 25%

Reviewer: Relative to 120, that is a 25% increase.

Turn 2. Thirty divided by the reference value one hundred twenty equals twenty-five percent.

3. spread

Analyst: The four-percent CV describes within-run spread.

Turn 3. The coefficient of variation concerns relative spread, not the change between means.

4. criteria

Reviewer: A formal acceptance decision still needs the applicable criteria.

Turn 4. The briefing supplies no acceptance criteria against which to make that decision.

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02 / Answers and explanations / continued

F / Rebuild the exchange

1. Rebuild the exchange from "Tight wells, shifting days". Chen: "Thanks. Is the shift enough to call the assay failed? I cannot find the intended-use limits in this review pack." Imani: [missing response] Chen: "Someone offered to rescale every day's mean to one hundred. It would remove the visible shift, but would it resolve the performance question?" Which response belongs in the gap?

D. We need the applicable acceptance criterion. Do not invent a pass or failure threshold from this chart; report the between-day difference as under investigation.

A Not here. This line belongs to turn 2, after Chen says: "Every run has a five-percent CV, so I kept fully reproducible in the summary. What am I missing before we show this to the project team?" It addresses that point, not the missing turn in the supplied exchange.

B Not here. This line belongs to turn 10, after Chen says: "All three runs were in this laboratory. Is between-day reproducibility the clearest heading, or would another term make the conditions more precise?" It addresses that point, not the missing turn in the supplied exchange.

C Not here. This line belongs to turn 4, after Chen says: "So the points can be tightly grouped each day while the groups move? I treated the repeated percentage as evidence of an unchanged result." It addresses that point, not the missing turn in the supplied exchange.

D Correct. This is Imani's response in turn 14. It connects Chen's preceding point with Chen's follow-up. An acceptance criterion supplies the predefined requirement needed for a formal performance judgment.

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03 / Answers and explanations

A / Read the situation

A1. Which claim is supported by the supplied study?

B. The test met predefined analytical criteria over the assessed range and plasma conditions.

The supplied study concerns measurement performance in a defined analytical setting.

[Return to the exercise, page 27](#)

A2. What evidence is absent?

B. A study establishing prediction of response to B17

The briefing expressly says response prediction has not been established.

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A3. Which proposed use requires additional support?

C. Selecting participants on an asserted predictive role

Patient selection based on response prediction goes beyond the supplied analytical evidence.

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D / Response choices

D1. Which description matches the supplied evidence?

C. The test met analytical criteria from 2 to 20 research units; prediction of B17 response is unestablished.

The correct description separates the completed analytical evaluation from the unestablished clinical relationship.

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D2. Why is a predictive label premature?

D. No study has established differing B17 response associated with the marker.

A predictive claim requires evidence about the intervention-related response, which the brief says is absent.

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03 / Answers and explanations / continued

D3. A colleague needs the term for this meaning: Establishing that a test adequately measures its intended analyte for the stated use. Which term fits?

D. analytical validation

A Not here. reportable range: The interval over which results can be appropriately reported under the method. The usual combination is "specify the reportable range".

B Not here. pharmacodynamic biomarker: A marker indicating biological response after exposure to an intervention. The usual combination is "measure a pharmacodynamic biomarker".

C Not here. positive predictive value: The proportion of positive test results that correspond to the target condition. The usual combination is "interpret positive predictive value".

D Correct. analytical validation: Establishing that a test adequately measures its intended analyte for the stated use. The usual combination is "complete analytical validation".

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D4. Rebuild the exchange from "Validated for which use?". Sara: "We should state the planned decision explicitly, then. The proposed use is selecting participants for the B17 program, not simply reporting protein concentration in a research sample." Noah: [missing response] Sara: "What should replace validated predictive biomarker in the current deck? I do not want to lose the analytical achievement while correcting the clinical overstatement." Which response belongs in the gap?

B. That is the context of use that needs supporting evidence. A reliable measurement can be necessary without being sufficient for the clinical decision being proposed.

A Not here. This line belongs to turn 12, after Sara says: "Suppose another study later associates the protein with faster disease progression. Would that automatically make it predictive for B17?" It addresses that point, not the missing turn in the supplied exchange.

B Correct. This is Noah's response in turn 6. It connects Sara's preceding point with Sara's follow-up. Context of use specifies the purpose and setting of the proposed biomarker application.

C Not here. This line belongs to turn 2, after Sara says: "The slide says validated predictive biomarker and then proposes selecting participants by the protein value. Can you tell me which part of that statement our study establishes?" It addresses that point, not the missing turn in the supplied exchange.

D Not here. This line belongs to turn 8, after Sara says: "What should replace validated predictive biomarker in the current deck? I do not want to lose the analytical achievement while correcting the clinical overstatement." It addresses that point, not the missing turn in the supplied exchange.

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E / Conversation

1. analytical validation

Turn 2. Analytical validation concerns the test's measurement performance under its specified conditions and intended analytical use.

03 / Answers and explanations / continued

2. clinical validation

Turn 4. Clinical validation would establish the relationship to the proposed clinical concept, here B17 response prediction.

3. context of use

Turn 6. Context of use specifies the purpose and setting of the proposed biomarker application.

4. analyte

Turn 8. The analyte is the substance measured, allowing a precise analytical claim without an unsupported predictive label.

5. decision threshold

Turn 10. A decision threshold needs support for its classification purpose and is not supplied by the midpoint of an analytical range.

6. prognostic biomarker

Turn 12. A prognostic biomarker concerns clinical course and does not automatically identify differential effects of a treatment.

7. predictive biomarker

Turn 14. A predictive biomarker identifies different likelihoods of effects from a particular intervention, requiring the relevant evidence.

8. matrix effect

Turn 16. Matrix effect describes how other sample components can influence measurement, limiting automatic transfer between sample types.

9. Biomarker qualification

Turn 18. Biomarker qualification is a formal, scoped acceptance process, not a synonym for an internal analytical result.

10. clinical utility

Turn 20. Clinical utility asks whether applying the test is useful in the specific care decision, beyond measurement alone.

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03 / Answers and explanations / continued

F / Accuracy and scope

F1. A colleague chooses 11 as an eligibility cutoff because it is the midpoint of 2 to 20. What evidence is missing?

D. Evidence supporting classification by that cutoff for the proposed B17 use

An in-range midpoint is an arithmetic property, not validation of a selection rule. The missing evidence concerns the intended response-related clinical use.

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F2. What would changing the sample from plasma require in the claim?

D. Appropriate evaluation of the changed matrix rather than automatic transfer of performance

Sample components can affect measurement, so the original conditions cannot be generalized automatically.

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F / Guided speaking

1. range

Scientist: Five to fifty is the assessed measurement range.

Turn 1. The supplied interval describes where measurement performance was evaluated.

2. threshold

Colleague: Twenty-five is a proposed decision threshold.

Turn 2. The proposed cutoff concerns an eligibility decision, not merely measurement capability.

3. unstudied

Scientist: Its relationship to response is unstudied.

Turn 3. The briefing explicitly says no response relationship has been studied.

4. selection

Colleague: The analytical result does not authorize participant selection.

Turn 4. Measurement performance alone does not support the proposed clinical selection rule.

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03 / Answers and explanations / continued

F / Rebuild the exchange

1. Rebuild the exchange from "Validated for which use?". Sara: "The distinction needs to appear in our terminology sheet. People use predict in everyday English for almost any association with a later event." Noah: [missing response] Sara: "Another team wants to transfer the assay to a different sample type. They believe the protein name being unchanged means the measurement evidence transfers automatically." Which response belongs in the gap?

D. In this development claim, a predictive biomarker relates to the effect of a particular intervention. We should define the intended scientific meaning rather than assume the everyday word settles it.

A Not here. This line belongs to turn 20, after Sara says: "I will remove validated predictive biomarker and the implied selection rule. Please give me wording that preserves the analytical result and names the clinical question still open." It addresses that point, not the missing turn in the supplied exchange.

B Not here. This line belongs to turn 10, after Sara says: "Why did the team choose ten units as the cutoff? Being inside the measurement range does not tell us who is likely to respond to B17." It addresses that point, not the missing turn in the supplied exchange.

C Not here. This line belongs to turn 18, after Sara says: "And an internal study meeting its criteria is not the same as receiving formal acceptance for every possible regulatory use. We should remove qualified from that sentence too." It addresses that point, not the missing turn in the supplied exchange.

D Correct. This is Noah's response in turn 14. It connects Sara's preceding point with Sara's follow-up. A predictive biomarker identifies different likelihoods of effects from a particular intervention, requiring the relevant evidence.

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04 / Answers and explanations

A / Read the situation

A1. What is the reported comparison?

C. A 20% lower mean model-endpoint value in 12 treated animals versus 12 controls at one exposure

The brief describes an animal-model mean endpoint comparison, not a human outcome.

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A2. What is known about blinding?

C. It is not documented in the supplied summary.

The summary's omission leaves blinding status unestablished rather than proving either condition.

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A3. Which conclusion is unsupported?

D. Human benefit has been proved.

No human outcome data are supplied, so the animal result cannot establish human benefit.

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D / Response choices

D1. Which sentence best represents the result?

A. At one exposure, the treated animal group had a 20% lower mean model endpoint than controls; human benefit is unestablished.

The supported sentence preserves the model, comparison, exposure limit, and absence of human evidence.

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D2. What does the missing blinding information mean?

A. The review needs clarification from the study record.

An omitted design detail needs verification rather than an assumption about how the study was conducted.

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04 / Answers and explanations / continued

D3. A colleague needs the term for this meaning: Allocation by a chance-based process to reduce systematic selection differences. Which term fits?

D. randomization

A Not here. tolerability: How adverse effects affect the ability to tolerate an intervention. The usual combination is "report tolerability findings".

B Not here. pharmacodynamics: The biological effects of an intervention and their relationship to exposure. The usual combination is "evaluate pharmacodynamics".

C Not here. translational uncertainty: Uncertainty in applying findings from one biological setting to another. The usual combination is "communicate translational uncertainty".

D Correct. randomization: Allocation by a chance-based process to reduce systematic selection differences. The usual combination is "document randomization".

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D4. Rebuild the exchange from "A model effect is not proof of human benefit". Zoe: "I see randomized allocation, but nothing about assessor blinding. Can you obtain that record before anyone adds blinded to the summary?" Amir: [missing response] Zoe: "I will request that detail from the study team. An omission in this summary does not prove the assessors knew the assignments, but it leaves the status unclear." Which response belongs in the gap?

D. Randomization and assessor blinding are separate design features. The first is documented here; the second is not stated, so we need clarification rather than an assumption.

A Not here. This line belongs to turn 2, after Zoe says: "The development slide says this is proof of human benefit. The reported model effect is encouraging, but I need a sentence that will survive a detailed package review." It addresses that point, not the missing turn in the supplied exchange.

B Not here. This line belongs to turn 16, after Zoe says: "What about the sentence saying the favorable endpoint establishes safety? I assume the full safety question requires different information and appropriate professional review." It addresses that point, not the missing turn in the supplied exchange.

C Not here. This line belongs to turn 4, after Zoe says: "We should say it was an animal model in the headline, not leave the audience to find that in a footnote after hearing a clinical claim." It addresses that point, not the missing turn in the supplied exchange.

D Correct. This is Amir's response in turn 6. It connects Zoe's preceding point with Zoe's follow-up. Randomization concerns chance-based allocation and does not establish whether assessors knew group assignments.

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04 / Answers and explanations / continued

E / Conversation

1. efficacy endpoint

Turn 2. The efficacy endpoint is the defined model measurement, not a directly measured human clinical outcome.

2. model relevance

Turn 4. Model relevance concerns how the experimental system relates to the development question without equating it with people.

3. Randomization

Turn 6. Randomization concerns chance-based allocation and does not establish whether assessors knew group assignments.

4. study report

Turn 8. The full study report provides methods and results needed to verify details omitted from a short summary.

5. uncertainty interval

Turn 10. An uncertainty interval expresses the estimate's uncertainty under the relevant analytical method.

6. exposure-response relationship

Turn 12. An exposure-response relationship requires evidence about how effects vary with exposure, not one tested condition alone.

7. pharmacokinetics

Turn 14. Pharmacokinetics concerns the substance's disposition over time and helps distinguish dose from resulting exposure.

8. toxicology

Turn 16. Toxicology concerns harmful effects and cannot be replaced by a favorable efficacy-endpoint result.

9. safety margin

Turn 18. A safety margin needs a justified comparison of relevant levels, which the supplied facts do not provide.

04 / Answers and explanations / continued

10. translational uncertainty

Turn 20. Translational uncertainty limits the extension from the tested model to another biological or clinical setting.

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F / Accuracy and scope

F1. Which addition would directly clarify uncertainty around the reported 20% model-endpoint difference?

D. The underlying group results and a justified uncertainty analysis

Group sizes and randomization matter but do not alone quantify uncertainty in the observed difference. The results and appropriate analysis address that question; a target population does not replace them.

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F2. Which distinction is accurate?

A. Administered dose and measured exposure are related but not identical concepts.

Dose describes administration, while exposure describes the substance reaching the system over time.

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F / Guided speaking

1. allocation

Scientist: Random allocation is documented.

Turn 1. The supplied summary explicitly describes random assignment to groups.

2. unstated

Reviewer: Assessor blinding remains unstated.

Turn 2. The summary gives no information establishing the assessors' blinding status.

3. record

Scientist: We need the relevant study record.

Turn 3. The underlying study documentation can clarify the omitted design detail.

4. verification

Reviewer: Neither proposed label is supported without verification.

Turn 4. Both fully blinded and definitely unblinded exceed the currently supplied evidence.

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04 / Answers and explanations / continued

F / Rebuild the exchange

1. Rebuild the exchange from "A model effect is not proof of human benefit". Zoe: "We also need to separate an administered dose from what reaches the relevant biological system. Those terms are being used interchangeably in the notes." Amir: [missing response] Zoe: "What about the sentence saying the favorable endpoint establishes safety? I assume the full safety question requires different information and appropriate professional review." Which response belongs in the gap?

C. The pharmacokinetics information addresses the disposition and exposure over time. The biological effect belongs to the pharmacodynamic question; neither can be replaced by a vague statement that the dose worked.

A Not here. This line belongs to turn 12, after Zoe says: "The team tested one exposure. That can establish a result under that condition, but it cannot show the whole pattern across lower and higher exposures." It addresses that point, not the missing turn in the supplied exchange.

B Not here. This line belongs to turn 8, after Zoe says: "I will request that detail from the study team. An omission in this summary does not prove the assessors knew the assignments, but it leaves the status unclear." It addresses that point, not the missing turn in the supplied exchange.

C Correct. This is Amir's response in turn 14. It connects Zoe's preceding point with Zoe's follow-up. Pharmacokinetics concerns the substance's disposition over time and helps distinguish dose from resulting exposure.

D Not here. This line belongs to turn 10, after Zoe says: "The twenty-percent difference also appears without an interval. I cannot tell how much uncertainty surrounds the estimate from the headline alone." It addresses that point, not the missing turn in the supplied exchange.

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05 / Answers and explanations

A / Read the situation

A1. What was demonstrated?

C. Harvest titer of 0.8 g/L in two 1-liter runs

The evidence is limited to harvest titer in the two specified small runs.

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A2. What does 0.8 g/L multiplied by 200 liters give under the stated assumption?

C. A hypothetical 160 grams at harvest before downstream losses

The arithmetic estimates harvest quantity if the same titer holds; recovery and quality are separate.

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A3. Which evidence remains missing?

D. Larger-scale performance, downstream recovery, and relevant quality results

The briefing expressly leaves those larger-scale and finished-product conditions unestablished.

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D / Response choices

D1. Which forecast is appropriately qualified?

B. If 0.8 g/L holds at 200 liters, harvest quantity would be 160 grams before recovery and quality evaluation.

The qualified forecast states its titer assumption, process stage, and unresolved finished-product conditions.

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D2. If a separate hypothetical process retains 70% of 160 grams, how much remains after that step?

A. 112 grams

Multiplying one hundred sixty by zero point seven gives one hundred twelve grams.

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05 / Answers and explanations / continued

D3. A colleague needs the term for this meaning: Stages that recover and purify material after production. Which term fits?

C. downstream processing

A Not here. scale-up: Increasing the size or production capacity of a process. The usual combination is "evaluate scale-up risks".

B Not here. comparability: Assessment that a change does not adversely affect relevant product quality, safety, or efficacy. The usual combination is "establish a comparability strategy".

C Correct. downstream processing: Stages that recover and purify material after production. The usual combination is "evaluate downstream processing".

D Not here. potency: A measure of biological activity relevant to the product's function. The usual combination is "evaluate product potency".

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D4. Rebuild the exchange from "Two small runs do not prove the large process". Ben: "What would change the amount after harvest? The table currently carries all 160 grams straight through purification without showing any loss." Hana: [missing response] Ben: "If a later run did match the concentration, could I at least use quality confirmed? The slide needs a short status for the review." Which response belongs in the gap?

A. It omits downstream recovery. We need the retained fraction for the relevant stages, not an implicit assumption that all harvested material reaches the end.

A Correct. This is Hana's response in turn 6. It connects Ben's preceding point with Ben's follow-up. Recovery describes the proportion retained through specified downstream stages and affects the final quantity.

B Not here. This line belongs to turn 10, after Ben says: "So an equal number of grams does not necessarily mean an equal biological effect. That distinction needs to survive when this becomes a commercial forecast." It addresses that point, not the missing turn in the supplied exchange.

C Not here. This line belongs to turn 8, after Ben says: "If a later run did match the concentration, could I at least use quality confirmed? The slide needs a short status for the review." It addresses that point, not the missing turn in the supplied exchange.

D Not here. This line belongs to turn 2, after Ben says: "I have a production slide promising 160 grams of acceptable finished product at 200 liters. That comes from the two one-liter runs. Can we support it?" It addresses that point, not the missing turn in the supplied exchange.

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E / Conversation

1. titer

Turn 2. Titer is concentration at the specified harvest stage, not a quantity of finished released material.

05 / Answers and explanations / continued

2. scale-up

Turn 4. Scale-up changes process size and requires relevant performance evidence rather than automatic extrapolation from small runs.

3. recovery

Turn 6. Recovery describes the proportion retained through specified downstream stages and affects the final quantity.

4. critical quality attribute

Turn 8. Critical quality attributes concern properties necessary for intended quality, beyond the amount produced.

5. Potency

Turn 10. Potency measures relevant biological activity and is not established solely by product concentration.

6. mass transfer

Turn 12. Mass transfer concerns movement within the system and may behave differently when the process scale changes.

7. scale-down model

Turn 14. A scale-down model can represent selected larger-process behavior when its relevance is appropriately established.

8. change control

Turn 16. Change control provides the formal review and traceability needed when process changes are proposed or implemented.

9. comparability

Turn 18. Comparability requires assessment of relevant product consequences of a change, not agreement in a single output alone.

10. CMC

Turn 20. CMC is the chemistry, manufacturing, and controls package connecting process performance with product quality.

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05 / Answers and explanations / continued

F / Accuracy and scope

F1. Which item is a quality question rather than simply a quantity calculation?

B. Whether relevant potency and impurity attributes remain appropriate

Potency and impurity attributes concern product quality, not only arithmetic output.

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F2. Both one-liter runs have the same titer. Which proposed summary overstates the demonstrated scope?

C. Matching titer establishes larger-scale quality comparability.

Equal small-run concentration is not evidence for all relevant larger-scale quality attributes. The other statements retain the observed scale or explicitly identify the open assumptions.

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F / Guided speaking

1. fifty

Scientist: The harvest contains fifty grams.

Turn 1. One hundred liters multiplied by zero point five grams per liter equals fifty grams.

2. forty

Reviewer: At eighty-percent recovery, forty grams remain.

Turn 2. Eighty percent of fifty grams equals forty grams after the specified step.

3. release

Scientist: That is a quantity calculation, not a release decision.

Turn 3. The briefing gives no quality review or authorization releasing the material.

4. separate

Reviewer: Keep the relevant product-quality evidence separate.

Turn 4. The amount retained does not by itself establish the relevant quality attributes.

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05 / Answers and explanations / continued

F / Rebuild the exchange

1. Rebuild the exchange from "Two small runs do not prove the large process". Ben: "Can we still use the small system to investigate risks? I do not want to discard two useful runs because they answer a narrower question." Hana: [missing response] Ben: "I will attach the process versions and batch records to the transfer pack. Which route keeps the proposed changes and their review traceable?" Which response belongs in the gap?

B. We can establish what a scale-down model represents. Its value depends on the relevant behavior demonstrated, not merely on using a smaller vessel.

A Not here. This line belongs to turn 16, after Ben says: "I will attach the process versions and batch records to the transfer pack. Which route keeps the proposed changes and their review traceable?" It addresses that point, not the missing turn in the supplied exchange.

B Correct. This is Hana's response in turn 14. It connects Ben's preceding point with Ben's follow-up. A scale-down model can represent selected larger-process behavior when its relevance is appropriately established.

C Not here. This line belongs to turn 10, after Ben says: "So an equal number of grams does not necessarily mean an equal biological effect. That distinction needs to survive when this becomes a commercial forecast." It addresses that point, not the missing turn in the supplied exchange.

D Not here. This line belongs to turn 2, after Ben says: "I have a production slide promising 160 grams of acceptable finished product at 200 liters. That comes from the two one-liter runs. Can we support it?" It addresses that point, not the missing turn in the supplied exchange.

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06 / Answers and explanations

A / Read the situation

A1. Which agreement is signed?

D. The confidentiality agreement

The brief states that confidentiality is agreed while the material-transfer terms remain a draft.

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A2. Which issue remains unresolved?

B. Permitted use and publication review, among other material-transfer terms

The briefing explicitly identifies the listed terms as unresolved.

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A3. What does ownership of a related patent establish about third-party rights here?

B. It does not by itself establish freedom to operate.

A party's own patent does not automatically resolve rights held by others.

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D / Response choices

D1. Which response best fits the shipment question?

B. The MTA terms remain unresolved, so seek the required review and authorization before treating shipment as approved.

The brief establishes only a signed confidentiality agreement and unfinished transfer terms.

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D2. Which review question concerns permitted use rather than a different transfer term?

C. Which named bench assessments may the recipient perform with the protein?

Permitted use defines the recipient's authorized activities. The other questions concern onward transfer, publication review, and ownership; each is important but distinct.

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06 / Answers and explanations / continued

D3. A colleague needs the term for this meaning: Legal identification of the people who contributed to a claimed invention. Which term fits?

A. inventorship

A Correct. inventorship: Legal identification of the people who contributed to a claimed invention. The usual combination is "assess inventorship".

B Not here. freedom to operate: Whether proposed acts can proceed without infringing relevant third-party rights. The usual combination is "obtain a scoped freedom-to-operate review".

C Not here. permitted use: The activities authorized for the material or rights under the agreement. The usual combination is "define permitted use".

D Not here. territory: The geographic scope of a right or permission. The usual combination is "specify the territory".

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D4. Rebuild the exchange from "A confidentiality agreement is not a material license". Julia: "The intended work is limited to three named assessments. The recipient also mentioned asking a separate laboratory to help, which is not addressed in the draft." Ravi: [missing response] Julia: "We also need to clarify what happens to discoveries made during the evaluation. Each team is bringing existing methods and information to the work." Which response belongs in the gap?

A. Define the permitted use precisely and address any onward transfer. The scientific plan should match the scope being reviewed, including which organizations would actually handle the material.

A Correct. This is Ravi's response in turn 6. It connects Julia's preceding point with Julia's follow-up. Permitted use identifies which activities the recipient is authorized to perform under the agreement.

B Not here. This line belongs to turn 14, after Julia says: "They also asked whether access to the material means they can use our practical methods in a later unrelated project. That sounds broader than this evaluation." It addresses that point, not the missing turn in the supplied exchange.

C Not here. This line belongs to turn 4, after Julia says: "I had assumed the signed confidentiality document covered the exchange. It lets us discuss the work, but that may be different from permission to use the material." It addresses that point, not the missing turn in the supplied exchange.

D Not here. This line belongs to turn 10, after Julia says: "If a new invention results, naming the people who contributed is not necessarily the same as deciding which organization will own the resulting rights." It addresses that point, not the missing turn in the supplied exchange.

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E / Conversation

1. material transfer agreement

Turn 2. The material transfer agreement governs the proposed tangible-material transfer and remains unfinished in this case.

06 / Answers and explanations / continued

2. nondisclosure agreement

Turn 4. A nondisclosure agreement addresses specified confidential information and does not automatically settle material-use permission.

3. permitted use

Turn 6. Permitted use identifies which activities the recipient is authorized to perform under the agreement.

4. background IP

Turn 8. Background IP identifies pre-existing intellectual property brought into the collaboration under the agreed definitions.

5. Inventorship

Turn 10. Inventorship identifies qualifying contributors to a claimed invention and is distinct from ownership of the rights.

6. publication review

Turn 12. Publication review is the agreed process for examining proposed disclosure, with its purpose and timing specified.

7. know-how

Turn 14. Know-how concerns practical technical information whose permitted use may differ from possession of a material.

8. freedom to operate

Turn 16. Freedom to operate concerns the proposed acts and relevant rights of others, not merely ownership of one's own patent.

9. third-party rights

Turn 18. Third-party rights are held outside these two partners and can remain relevant to the proposed activities.

10. governing agreement

Turn 20. The governing agreement supplies the actual applicable terms for the authorized collaboration rather than an informal assumption.

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06 / Answers and explanations / continued

F / Accuracy and scope

F1. Why does a related owned patent not settle FTO?

D. Other parties may hold relevant rights affecting the proposed acts.

Rights held by others can remain relevant despite ownership of a separate patent.

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F2. Which statement preserves the publication issue?

B. The publication-review process and timing remain to be agreed.

The supplied draft has unresolved publication terms, so neither unrestricted release nor permanent prohibition is established.

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F / Guided speaking

1. evaluation

Scientist: The stated purpose is evaluation.

Turn 1. The supplied permission concerns evaluating the confidential method summary.

2. permitted

Partner: Commercial use is not established as permitted.

Turn 2. The brief expressly says commercial-use permission has not been agreed.

3. unresolved

Scientist: Onward disclosure also remains unresolved.

Turn 3. No onward-disclosure permission is supplied, so it cannot be assumed.

4. terms

Partner: We need the actual governing terms.

Turn 4. The relevant permissions depend on the applicable agreement rather than access alone.

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06 / Answers and explanations / continued

F / Rebuild the exchange

1. Rebuild the exchange from "A confidentiality agreement is not a material license".

Julia: "They also asked whether access to the material means they can use our practical methods in a later unrelated project. That sounds broader than this evaluation." Ravi: [missing response] Julia: "Our team owns a related patent. Some colleagues think that means we can tell the partner there are no intellectual-property obstacles to any proposed use." Which response belongs in the gap?

C. Clarify any know-how being supplied and the authorized uses. Physical possession of a reference protein does not automatically settle rights in every method discussed alongside it.

A Not here. This line belongs to turn 10, after Julia says: "If a new invention results, naming the people who contributed is not necessarily the same as deciding which organization will own the resulting rights." It addresses that point, not the missing turn in the supplied exchange.

B Not here. This line belongs to turn 6, after Julia says: "The intended work is limited to three named assessments. The recipient also mentioned asking a separate laboratory to help, which is not addressed in the draft." It addresses that point, not the missing turn in the supplied exchange.

C Correct. This is Ravi's response in turn 14. It connects Julia's preceding point with Julia's follow-up. Know-how concerns practical technical information whose permitted use may differ from possession of a material.

D Not here. This line belongs to turn 4, after Julia says: "I had assumed the signed confidentiality document covered the exchange. It lets us discuss the work, but that may be different from permission to use the material." It addresses that point, not the missing turn in the supplied exchange.

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07 / Answers and explanations

A / Read the situation

A1. Why is the funding criterion not yet met?

A. Only two of the required three independent functional runs are complete.

The agreed criterion requires three consistent functional runs, and the third remains pending.

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A2. What is the simple base-case runway at unchanged net burn?

B. Ten months

Twelve million divided by one point two million per month equals ten months.

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A3. How should the \$0.3 million proposal be described?

C. Additional proposed funding, not yet approved or included in the base case

The brief explicitly leaves the proposed budget unapproved and outside the current base case.

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D / Response choices

D1. Which opening is most decision-ready?

A. Two functional runs are complete; the third required by the funding criterion is pending, and we request \$0.3 million for the defined follow-up.

The opening connects actual evidence, the unmet criterion, and the specific proposed decision.

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D2. What makes the ten-month runway conditional?

D. It assumes unchanged net burn and the stated available cash basis.

The arithmetic holds only under the cash and burn assumptions stated in the brief.

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07 / Answers and explanations / continued

D3. A colleague needs the term for this meaning: A defined decision to continue, stop, or redirect a program. Which term fits?

C. go/no-go decision

A Not here. run rate: A current rate projected over another period under stated assumptions. The usual combination is "qualify the run-rate estimate".

B Not here. dilution: Reduction in an existing owner's proportional interest following additional equity issuance. The usual combination is "explain potential dilution".

C Correct. go/no-go decision: A defined decision to continue, stop, or redirect a program. The usual combination is "support a go/no-go decision".

D Not here. board ask: The specific decision or support requested from the board. The usual combination is "state the board ask".

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D4. Rebuild the exchange from "Six experiments, one unfinished milestone". Daria: "We also need to revise the phrase fully de-risked. The completed work may reduce some uncertainty, but the pending functional result could still affect the direction." Miles: [missing response] Daria: "My request is the additional three-hundred-thousand-dollar budget for the defined follow-up. I am not asking for an unlimited commitment to every later development stage." Which response belongs in the gap?

D. Name the remaining scientific risk. Do not turn progress into a claim that every uncertainty has disappeared, particularly when the agreed evidence condition remains open.

A Not here. This line belongs to turn 16, after Daria says: "For the schedule, the third functional run is the key unresolved item. The board should understand how its outcome connects to the next program decision." It addresses that point, not the missing turn in the supplied exchange.

B Not here. This line belongs to turn 2, after Daria says: "The update opens with six experiments completed. That is accurate as an activity count, but I am concerned it makes the next funding milestone sound finished." It addresses that point, not the missing turn in the supplied exchange.

C Not here. This line belongs to turn 4, after Daria says: "Four of the six completed experiments are binding work. They support the program, but they do not replace the particular functional evidence required at this gate." It addresses that point, not the missing turn in the supplied exchange.

D Correct. This is Miles's response in turn 6. It connects Daria's preceding point with Daria's follow-up. Scientific risk concerns whether the biological or technical premise will hold, which completed activity alone cannot eliminate.

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07 / Answers and explanations / continued

E / Conversation

1. milestone criterion

Turn 2. The milestone criterion specifies three consistent independent functional runs rather than a total activity count.

2. evidence package

Turn 4. The evidence package organizes the relevant results for the decision without treating unlike experiments as interchangeable.

3. scientific risk

Turn 6. Scientific risk concerns whether the biological or technical premise will hold, which completed activity alone cannot eliminate.

4. board ask

Turn 8. The board ask is the specific bounded funding decision being requested, distinct from reporting completed work.

5. cash runway

Turn 10. Cash runway estimates the duration of available cash under the stated net-burn assumptions.

6. base case

Turn 12. The base case is the current central planning scenario, which excludes the unapproved additional proposal here.

7. contingent funding

Turn 14. Contingent funding depends on future conditions and is not equivalent to cash already received.

8. dependency

Turn 16. A dependency identifies the evidence or task on which the next decision relies.

9. downside case

Turn 18. A downside case shows the consequences of specified less-favorable assumptions without treating them as established outcomes.

10. decision record

Turn 20. The decision record preserves what the board actually decided and any conditions attached to it.

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07 / Answers and explanations / continued

F / Accuracy and scope

F1. The board packet counts six completed experiments against the three-run gate. What is the reporting error?

C. It combines different evidence categories although the criterion specifies functional runs.

Four binding experiments plus two functional runs is six activities, but only two match the specified category. The third functional run is still pending; a total count does not satisfy the gate.

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F2. What should happen if the new budget is approved?

D. Update the cash model for the actual spending assumptions and record the decision.

An approved additional spend changes planning inputs without establishing the experimental outcome.

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F / Guided speaking

1. six

Finance lead: The simple base-case runway is six months.

Turn 1. Nine million divided by one point five million per month equals six months.

2. burn

Program lead: That assumes an unchanged net burn.

Turn 2. The calculation holds only at the stated net cash-outflow rate.

3. excluded

Finance lead: The new project cost is currently excluded.

Turn 3. The briefing states that the proposed cost is outside the base case.

4. model

Program lead: Approval would require an updated cash model.

Turn 4. Adding approved spending requires the planning assumptions and resulting cash estimate to be updated.

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07 / Answers and explanations / continued

F / Rebuild the exchange

1. Rebuild the exchange from "Six experiments, one unfinished milestone". Daria: "There is also a proposed financing round later. We should keep that distinct from cash already available rather than use it to make the runway look longer today." Miles: [missing response] Daria: "For the schedule, the third functional run is the key unresolved item. The board should understand how its outcome connects to the next program decision." Which response belongs in the gap?

C. Correct. Treat any contingent funding according to its actual status. A plan to raise money is not a receipt, and an unmet scientific condition should remain visible.

A Not here. This line belongs to turn 2, after Daria says: "The update opens with six experiments completed. That is accurate as an activity count, but I am concerned it makes the next funding milestone sound finished." It addresses that point, not the missing turn in the supplied exchange.

B Not here. This line belongs to turn 4, after Daria says: "Four of the six completed experiments are binding work. They support the program, but they do not replace the particular functional evidence required at this gate." It addresses that point, not the missing turn in the supplied exchange.

C Correct. This is Miles's response in turn 14. It connects Daria's preceding point with Daria's follow-up. Contingent funding depends on future conditions and is not equivalent to cash already received.

D Not here. This line belongs to turn 12, after Daria says: "Show the proposed three hundred thousand separately. What happens to the forecast if the board approves it, given that the base case excludes it?" It addresses that point, not the missing turn in the supplied exchange.

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08 / Answers and explanations

A / Read the situation

A1. What is the proposed first-stage work?

C. A six-month nonclinical evaluation of T2 and T5

The stated initial proposal is limited to two targets and a six-month nonclinical evaluation.

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A2. What authority does Nina have?

A. Discuss a narrower proposal, not grant rights

The brief expressly limits Nina to discussion rather than granting rights.

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A3. What remains unapproved?

C. License, option, budget, and governance terms

The briefing identifies those substantive agreement terms as not approved.

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D / Response choices

D1. Which counterproposal fits Nina's authority?

C. Prepare a reviewed proposal limited to the two-target, six-month evaluation and explicitly unresolved terms.

Nina may discuss and prepare a narrower proposal but is not authorized to grant rights.

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D2. Why distinguish an option from a license?

B. An option concerns a defined opportunity to obtain rights, while a license grants specified permission.

The two arrangements confer different positions, and the actual terms determine their scope and exercise.

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08 / Answers and explanations / continued

D3. A colleague needs the term for this meaning: An agreement giving a defined opportunity to obtain specified rights on stated conditions. Which term fits?

B. option agreement

A Not here. termination right: A contractual ability to end an arrangement under defined conditions. The usual combination is "review termination rights".

B Correct. option agreement: An agreement giving a defined opportunity to obtain specified rights on stated conditions. The usual combination is "negotiate an option agreement".

C Not here. royalty: A payment calculated on an agreed basis for use of licensed rights. The usual combination is "define the royalty basis".

D Not here. territorial restriction: A geographic limit on the relevant rights or activities. The usual combination is "clarify territorial restrictions".

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D4. Rebuild the exchange from "Define the collaboration before granting exclusivity". Tomas: "Could we start with evaluation rights and secure a route to a later commercial license if the results meet agreed criteria?" Nina: [missing response] Tomas: "We would need to know what evidence qualifies and when we must decide. Otherwise the option could be too uncertain to support a meaningful investment." Which response belongs in the gap?

D. We can discuss an option agreement as a proposal. It would need clear scope, conditions, and approval; a possible future option is not already a commercial license.

A Not here. This line belongs to turn 4, after Tomas says: "Our immediate interest is those two targets. We also see possible applications beyond them, and we would prefer not to renegotiate every time the opportunity develops." It addresses that point, not the missing turn in the supplied exchange.

B Not here. This line belongs to turn 12, after Tomas says: "We can bring specialist capability and funding for the evaluation, but the division of costs has not been discussed. That needs to be part of the same proposal." It addresses that point, not the missing turn in the supplied exchange.

C Not here. This line belongs to turn 16, after Tomas says: "Could a joint committee handle routine technical decisions? I do not want a small adjustment to require another executive negotiation every time." It addresses that point, not the missing turn in the supplied exchange.

D Correct. This is Nina's response in turn 6. It connects Tomas's preceding point with Tomas's follow-up. An option agreement could provide a defined opportunity to obtain rights later under specified conditions.

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E / Conversation

1. exclusivity scope

Turn 2. Exclusivity scope defines what is protected and cannot be inferred from the broad word exclusive alone.

08 / Answers and explanations / continued

2. field restriction

Turn 4. A field restriction limits the proposed rights to specified applications rather than every possible platform use.

3. option agreement

Turn 6. An option agreement could provide a defined opportunity to obtain rights later under specified conditions.

4. option exercise

Turn 8. Option exercise is the use of the option in accordance with its specified timing and conditions.

5. reserved rights

Turn 10. Reserved rights are the uses or permissions retained rather than included in the proposed grant.

6. cost sharing

Turn 12. Cost sharing allocates the defined evaluation expenses and cannot be assumed from general interest in partnering.

7. diligence obligation

Turn 14. A diligence obligation defines the agreed efforts or progress expected rather than leaving exclusivity without operational commitments.

8. joint steering committee

Turn 16. A joint steering committee can coordinate the collaboration, but its authority must be specified in the agreement.

9. rights reversion

Turn 18. Rights reversion concerns the return or cessation of specified rights under agreed end conditions.

10. term sheet

Turn 20. A term sheet summarizes proposed principal terms whose binding effect must be explicitly reviewed.

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08 / Answers and explanations / continued

F / Accuracy and scope

F1. A draft names a joint steering committee but gives it no powers. Which question addresses that gap?

D. Who may approve scope changes, budgets, and continuation decisions?

Governance requires actual decision authority and rules. Targets, territory, and data access are separate scope questions and do not establish what the committee may decide.

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F2. What should the meeting record say?

B. The parties will prepare a narrower proposal; no rights grant is approved.

The record must preserve discussion status and the absence of an authorized grant.

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F / Guided speaking

1. discussion

Partner: The possible option is still under discussion.

Turn 1. The briefing states that the option is being discussed and is not signed.

2. signed

Lead: No option has been signed.

Turn 2. The supplied facts explicitly deny a signed option agreement.

3. granted

Partner: No commercial license has been granted.

Turn 3. The briefing states that no license grant has occurred.

4. status

Lead: The meeting note must preserve that status.

Turn 4. The note should reflect discussion rather than falsely report acquired commercial rights.

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08 / Answers and explanations / continued

F / Rebuild the exchange

1. Rebuild the exchange from "Define the collaboration before granting exclusivity".

Tomas: "If we seek some exclusivity, you will want assurance that the work moves forward. We should discuss what commitments would accompany that protection."

Nina: [missing response] **Tomas:** "Could a joint committee handle routine technical decisions? I do not want a small adjustment to require another executive negotiation every time." Which response belongs in the gap?

C. Appropriate diligence obligation terms can address that, subject to review. The proposal should state the expected progress and consequences rather than rely on a general promise to try.

A Not here. This line belongs to turn 4, after Tomas says: "Our immediate interest is those two targets. We also see possible applications beyond them, and we would prefer not to renegotiate every time the opportunity develops." It addresses that point, not the missing turn in the supplied exchange.

B Not here. This line belongs to turn 2, after Tomas says: "Before we commit resources, we would like worldwide exclusive rights across the platform. We do not want to fund the work while a competitor receives the same opportunity." It addresses that point, not the missing turn in the supplied exchange.

C Correct. This is Nina's response in turn 14. It connects Tomas's preceding point with Tomas's follow-up. A diligence obligation defines the agreed efforts or progress expected rather than leaving exclusivity without operational commitments.

D Not here. This line belongs to turn 6, after Tomas says: "Could we start with evaluation rights and secure a route to a later commercial license if the results meet agreed criteria?" It addresses that point, not the missing turn in the supplied exchange.

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Review 1 / Explanations

Cumulative review

1. A colleague needs the term for this meaning: A type of therapeutic or technological approach. Which term fits?

B. modality

A Not here. generalizability: The extent to which a finding applies beyond the tested setting. The usual combination is "assess generalizability".

B Correct. modality: A type of therapeutic or technological approach. The usual combination is "compare therapeutic modalities".

C Not here. cell line: A maintained population of cells used for research. The usual combination is "characterize the cell line".

D Not here. assay interference: An effect on the measurement system that can distort the apparent result. The usual combination is "investigate assay interference".

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2. A colleague needs the term for this meaning: A measure of how observations are spread around their mean. Which term fits?

D. standard deviation

A Not here. calibration: Establishing the relationship between measurement response and reference values. The usual combination is "verify calibration records".

B Not here. edge effect: A position-related difference at the outer wells of a plate. The usual combination is "check for an edge effect".

C Not here. assay development: Designing and refining a measurement method for a specified purpose. The usual combination is "plan assay development".

D Correct. standard deviation: A measure of how observations are spread around their mean. The usual combination is "calculate the standard deviation".

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Review 1 / Explanations / continued

3. Rebuild the exchange from "One cell line, three proposed diseases". Leo: "What would the next study tell us that another reporter run would not? The funding request needs a scientific question, not just a larger sample count." Nia: [missing response] Leo: "We should be clear that you are asking to test that distinction, not promising that the second method will confirm the first. Otherwise the milestone is misleading." Which response belongs in the gap?

B. It should include an orthogonal assay addressing the underlying biology. A different measurement approach would help distinguish a relevant biological effect from a feature of this reporter system.

A Not here. This line belongs to turn 20, after Leo says: "I will remove the three-disease claim and request the bounded follow-up. Keep the forty-percent result beside the actual cell system so the claim cannot drift again." It addresses that point, not the missing turn in the supplied exchange.

B Correct. This is Nia's response in turn 10. It connects Leo's preceding point with Leo's follow-up. An orthogonal assay uses a different measurement approach to examine the underlying biological question.

C Not here. This line belongs to turn 2, after Leo says: "The headline says our platform has proven activity across three diseases. It sounds strong, but I want to know whether each part of that claim is supported." It addresses that point, not the missing turn in the supplied exchange.

D Not here. This line belongs to turn 14, after Leo says: "How do we describe the proposed disease expansion without making it sound like a result? I want an ambitious but defensible sentence in the investor discussion." It addresses that point, not the missing turn in the supplied exchange.

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Review 1 / Explanations / continued

4. Rebuild the exchange from "Tight wells, shifting days". Chen: "Then retain the original readings and show how any adjusted result was derived. The unadjusted plot should not disappear from the package." Imani: [missing response] Chen: "I will show the three means beside their CVs, correct the percentage, and list the missing criteria and records. No validation conclusion yet." Which response belongs in the gap?

C. Agreed. Include the calibration records too, so we can trace the measurement basis rather than infer it from the graph alone.

A Not here. This line belongs to turn 10, after Chen says: "All three runs were in this laboratory. Is between-day reproducibility the clearest heading, or would another term make the conditions more precise?" It addresses that point, not the missing turn in the supplied exchange.

B Not here. This line belongs to turn 12, after Chen says: "I also wrote that day three rose twenty percent from day two. I divided twenty-five by the final value of one hundred twenty-five." It addresses that point, not the missing turn in the supplied exchange.

C Correct. This is Imani's response in turn 18. It connects Chen's preceding point with Chen's follow-up. Calibration records describe the relationship to reference values and may help explain measurement differences.

D Not here. This line belongs to turn 6, after Chen says: "We intended the same nominal control level. Could the newest operator explain the shift? That was the first suggestion in yesterday's meeting." It addresses that point, not the missing turn in the supplied exchange.

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Review 2 / Explanations

Cumulative review

1. A colleague needs the term for this meaning: The defined purpose and setting in which a biomarker is to be used. Which term fits?

D. context of use

A Not here. predictive biomarker: A marker identifying differing likelihood of an effect from a particular intervention. The usual combination is "evaluate a predictive biomarker".

B Not here. fit for purpose: Adequate for a specifically defined intended use. The usual combination is "demonstrate fit-for-purpose performance".

C Not here. diagnostic specificity: The proportion without the target condition correctly identified as negative. The usual combination is "estimate diagnostic specificity".

D Correct. context of use: The defined purpose and setting in which a biomarker is to be used. The usual combination is "specify the context of use".

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2. A colleague needs the term for this meaning: The time course of a substance's absorption, distribution, metabolism, and elimination. Which term fits?

A. pharmacokinetics

A Correct. pharmacokinetics: The time course of a substance's absorption, distribution, metabolism, and elimination. The usual combination is "characterize pharmacokinetics".

B Not here. biodistribution: The pattern of a substance's presence across tissues or body compartments. The usual combination is "characterize biodistribution".

C Not here. good laboratory practice: A formal quality system for applicable nonclinical safety studies. The usual combination is "verify good laboratory practice status".

D Not here. preclinical package: The body of nonclinical evidence supporting a development review. The usual combination is "assemble a preclinical package".

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Review 2 / Explanations / continued

3. Rebuild the exchange from "Tight wells, shifting days". Chen: "All three runs were in this laboratory. Is between-day reproducibility the clearest heading, or would another term make the conditions more precise?" Imani: [missing response] Chen: "I also wrote that day three rose twenty percent from day two. I divided twenty-five by the final value of one hundred twenty-five." Which response belongs in the gap?

A. We are examining intermediate precision within this laboratory. State the days and conditions examined so the reader does not infer an interlaboratory study.

A Correct. This is Imani's response in turn 10. It connects Chen's preceding point with Chen's follow-up. Intermediate precision covers relevant variation within one laboratory, including between-day conditions.

B Not here. This line belongs to turn 4, after Chen says: "So the points can be tightly grouped each day while the groups move? I treated the repeated percentage as evidence of an unchanged result." It addresses that point, not the missing turn in the supplied exchange.

C Not here. This line belongs to turn 12, after Chen says: "I also wrote that day three rose twenty percent from day two. I divided twenty-five by the final value of one hundred twenty-five." It addresses that point, not the missing turn in the supplied exchange.

D Not here. This line belongs to turn 6, after Chen says: "We intended the same nominal control level. Could the newest operator explain the shift? That was the first suggestion in yesterday's meeting." It addresses that point, not the missing turn in the supplied exchange.

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4. Rebuild the exchange from "A model effect is not proof of human benefit". Zoe: "Nor should we invent a human safety margin from this one model result. We do not have the necessary comparison or its scientific justification." Amir: [missing response] Zoe: "I will keep the result explicitly nonclinical and request the missing uncertainty and exposure information. Please also confirm the blinding status from the study records." Which response belongs in the gap?

B. Exactly. Any safety margin must state the compared quantities and supporting basis. A reassuring label cannot supply the missing exposure information or translation rationale.

A Not here. This line belongs to turn 4, after Zoe says: "We should say it was an animal model in the headline, not leave the audience to find that in a footnote after hearing a clinical claim." It addresses that point, not the missing turn in the supplied exchange.

B Correct. This is Amir's response in turn 18. It connects Zoe's preceding point with Zoe's follow-up. A safety margin needs a justified comparison of relevant levels, which the supplied facts do not provide.

C Not here. This line belongs to turn 2, after Zoe says: "The development slide says this is proof of human benefit. The reported model effect is encouraging, but I need a sentence that will survive a detailed package review." It addresses that point, not the missing turn in the supplied exchange.

D Not here. This line belongs to turn 20, after Zoe says: "I will keep the result explicitly nonclinical and request the missing uncertainty and exposure information. Please also confirm the blinding status from the study records." It addresses that point, not the missing turn in the supplied exchange.

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Review 3 / Explanations

Cumulative review

1. A colleague needs the term for this meaning: The production stages that generate the biological material. Which term fits?

B. upstream processing

A Not here. bioburden: The level of viable microorganisms associated with a material or process. The usual combination is "monitor bioburden".

B Correct. upstream processing: The production stages that generate the biological material. The usual combination is "characterize upstream processing".

C Not here. purity: The proportion or profile of intended material relative to impurities. The usual combination is "assess product purity".

D Not here. process characterization: Study of how process conditions affect performance and quality. The usual combination is "plan process characterization".

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2. A colleague needs the term for this meaning: The defined application area within which permission applies. Which term fits?

C. field of use

A Not here. patent claim: The legal wording defining the scope of protection sought or granted. The usual combination is "review relevant patent claims".

B Not here. nondisclosure agreement: An agreement governing specified confidential information. The usual combination is "review a nondisclosure agreement".

C Correct. field of use: The defined application area within which permission applies. The usual combination is "limit the field of use".

D Not here. intellectual property: Legally recognized rights in inventions, works, marks, or other protected subject matter. The usual combination is "identify relevant intellectual property".

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Review 3 / Explanations / continued

3. Rebuild the exchange from "A model effect is not proof of human benefit". Zoe: "The twenty-percent difference also appears without an interval. I cannot tell how much uncertainty surrounds the estimate from the headline alone." Amir: [missing response] Zoe: "The team tested one exposure. That can establish a result under that condition, but it cannot show the whole pattern across lower and higher exposures." Which response belongs in the gap?

C. We need the appropriate uncertainty interval or other specified analysis and the underlying results. A percentage by itself does not establish statistical significance or the reliability of the estimate.

A Not here. This line belongs to turn 12, after Zoe says: "The team tested one exposure. That can establish a result under that condition, but it cannot show the whole pattern across lower and higher exposures." It addresses that point, not the missing turn in the supplied exchange.

B Not here. This line belongs to turn 8, after Zoe says: "I will request that detail from the study team. An omission in this summary does not prove the assessors knew the assignments, but it leaves the status unclear." It addresses that point, not the missing turn in the supplied exchange.

C Correct. This is Amir's response in turn 10. It connects Zoe's preceding point with Zoe's follow-up. An uncertainty interval expresses the estimate's uncertainty under the relevant analytical method.

D Not here. This line belongs to turn 14, after Zoe says: "We also need to separate an administered dose from what reaches the relevant biological system. Those terms are being used interchangeably in the notes." It addresses that point, not the missing turn in the supplied exchange.

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Review 3 / Explanations / continued

4. Rebuild the exchange from "A confidentiality agreement is not a material license".
Julia: "Then our own patentability work and a third-party-rights review should not be presented as the same assessment. They answer different questions for the collaboration." **Ravi:** [missing response] **Julia:** "I will hold shipment and send the exact assessment list and laboratory names for review. The teams agree on the science; the transfer terms still need resolution." Which response belongs in the gap?

A. Yes. Examine relevant third-party rights through appropriately scoped professional review. A right we hold is not a universal permission to practice every related technology or distribute every associated material.

A Correct. This is Ravi's response in turn 18. It connects Julia's preceding point with Julia's follow-up. Third-party rights are held outside these two partners and can remain relevant to the proposed activities.

B Not here. This line belongs to turn 4, after Julia says: "I had assumed the signed confidentiality document covered the exchange. It lets us discuss the work, but that may be different from permission to use the material." It addresses that point, not the missing turn in the supplied exchange.

C Not here. This line belongs to turn 12, after Julia says: "The recipient wants to publish. Can the draft specify how review would work, including timing, without implying either immediate unrestricted publication or an unlimited veto?" It addresses that point, not the missing turn in the supplied exchange.

D Not here. This line belongs to turn 16, after Julia says: "Our team owns a related patent. Some colleagues think that means we can tell the partner there are no intellectual-property obstacles to any proposed use." It addresses that point, not the missing turn in the supplied exchange.

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Review 4 / Explanations

Cumulative review

1. A colleague needs the term for this meaning: The organized results and supporting records used for a decision. Which term fits?

C. evidence package

A Not here. dependency: An input or task that another activity relies on. The usual combination is "make dependencies explicit".

B Not here. cash runway: The estimated period before available cash is exhausted under stated assumptions. The usual combination is "estimate cash runway".

C Correct. evidence package: The organized results and supporting records used for a decision. The usual combination is "assemble the evidence package".

D Not here. financing round: A defined transaction or process to raise capital. The usual combination is "prepare for a financing round".

[Return to the exercise, page 102](#)

2. A colleague needs the term for this meaning: A limitation to specified applications or uses. Which term fits?

B. field restriction

A Not here. partnering thesis: The argument for why a collaboration could create value for both parties. The usual combination is "articulate the partnering thesis".

B Correct. field restriction: A limitation to specified applications or uses. The usual combination is "define a field restriction".

C Not here. development milestone: A defined development achievement linked to review or agreed consequences. The usual combination is "specify development milestones".

D Not here. governance: The agreed structures and rules for overseeing a collaboration. The usual combination is "define collaboration governance".

[Return to the exercise, page 102](#)

Review 4 / Explanations / continued

3. Rebuild the exchange from "A confidentiality agreement is not a material license".

Julia: "If a new invention results, naming the people who contributed is not necessarily the same as deciding which organization will own the resulting rights."

Ravi: [missing response] **Julia:** "The recipient wants to publish. Can the draft specify how review would work, including timing, without implying either immediate unrestricted publication or an unlimited veto?" Which response belongs in the gap?

D. Correct. Inventorship and ownership are different legal questions. We should not resolve either casually in an email saying that every new idea belongs to the team.

A Not here. This line belongs to turn 6, after Julia says: "The intended work is limited to three named assessments. The recipient also mentioned asking a separate laboratory to help, which is not addressed in the draft." It addresses that point, not the missing turn in the supplied exchange.

B Not here. This line belongs to turn 4, after Julia says: "I had assumed the signed confidentiality document covered the exchange. It lets us discuss the work, but that may be different from permission to use the material." It addresses that point, not the missing turn in the supplied exchange.

C Not here. This line belongs to turn 14, after Julia says: "They also asked whether access to the material means they can use our practical methods in a later unrelated project. That sounds broader than this evaluation." It addresses that point, not the missing turn in the supplied exchange.

D Correct. This is Ravi's response in turn 10. It connects Julia's preceding point with Julia's follow-up. Inventorship identifies qualifying contributors to a claimed invention and is distinct from ownership of the rights.

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Review 4 / Explanations / continued

4. Rebuild the exchange from "Define the collaboration before granting exclusivity". Tomas: "We should also describe what happens if the evaluation ends without a later license. Materials, data access, and any temporary restrictions need a clear position." Nina: [missing response] Tomas: "I will tell our team we are preparing a two-target proposal, not announcing worldwide exclusivity. Send me the open points so we can assign reviewers on our side." Which response belongs in the gap?

D. Address rights reversion and the relevant end-of-project obligations in the reviewed proposal. Do not assume that a temporary arrangement continues indefinitely because nobody discussed its end.

A Not here. This line belongs to turn 12, after Tomas says: "We can bring specialist capability and funding for the evaluation, but the division of costs has not been discussed. That needs to be part of the same proposal." It addresses that point, not the missing turn in the supplied exchange.

B Not here. This line belongs to turn 6, after Tomas says: "Could we start with evaluation rights and secure a route to a later commercial license if the results meet agreed criteria?" It addresses that point, not the missing turn in the supplied exchange.

C Not here. This line belongs to turn 8, after Tomas says: "We would need to know what evidence qualifies and when we must decide. Otherwise the option could be too uncertain to support a meaningful investment." It addresses that point, not the missing turn in the supplied exchange.

D Correct. This is Nina's response in turn 18. It connects Tomas's preceding point with Tomas's follow-up. Rights reversion concerns the return or cessation of specified rights under agreed end conditions.

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Additional case 1 / Explanations

Extended conversation

1. cell-line authentication

Turn 2. Cell-line authentication establishes identity through appropriate evidence; a matching label alone is not an identity check.

2. mycoplasma testing

Turn 5. Mycoplasma testing checks for a particular contamination concern; it is not interchangeable with establishing the cell line's identity.

3. passage history

Turn 8. Passage history records the sequence of cell subculturing and relevant lineage information; inconsistent counting needs clarification.

4. working cell bank

Turn 10. A working cell bank supplies routine work from a defined cell-bank lineage; its relationship to the source bank must remain traceable.

5. cross-contamination

Turn 12. Cross-contamination introduces material from another source and may not be excluded by normal-looking morphology alone.

6. provenance

Turn 16. Provenance identifies the material's origin and history; relabeling without resolving the discrepancy would hide that information.

[Return to the conversation, page 105](#)

Transfer exchange

1. stock

Scientist: This result belongs to the previously tested stock.

Turn 1. The record identifies the old stock and does not assess the new material.

Additional case 1 / Explanations / continued

2. history

Reviewer: Restore the correct link and retain the correction history.

Turn 2. Traceable correction preserves how the wrong association was identified and fixed.

3. unestablished

Scientist: Mark the new stock's test status as unestablished.

Turn 3. No assessment of the new stock has been supplied, so its status cannot be inferred.

4. questions

Reviewer: Keep identity and contamination as separate review questions.

Turn 4. Material identity and a specific contamination result are distinct evidence questions.

[Return to the conversation., page 108](#)

Additional case 2 / Explanations

Extended conversation

1. batch effect

Turn 2. A batch effect is systematic variation associated with processing groups rather than necessarily the biology under study.

2. confounding

Turn 4. Confounding means the biological group and processing batch vary together, preventing their separate effects from being identified from this design alone.

3. technical replicates

Turn 6. Technical replicates repeat measurement of the same biological material; they do not create additional independent biological samples.

4. Biological replicates

Turn 8. Biological replicates are independent biological samples that capture relevant biological variation rather than repeated readings of one sample.

5. balanced design

Turn 14. A balanced design distributes relevant biological groups across processing conditions so those factors are not automatically identical.

6. sample metadata

Turn 16. Sample metadata describe origin, grouping, processing, and other relevant characteristics needed to understand the analysis design.

[Return to the conversation, page 110](#)

Transfer exchange

1. replicates

Scientist: We have five donors, not ten independent biological replicates.

Turn 1. Repeating measurements of the same five donors does not add new independent donors.

Additional case 2 / Explanations / continued

2. readings

Analyst: The extra measurements provide technical repeat readings.

Turn 2. The repeated measurements add readings of existing biological material rather than new donor sources.

3. metadata

Scientist: Keep the donor-to-measurement links in the metadata.

Turn 3. Metadata must preserve which measurements came from the same donor or sample.

4. analysis

Analyst: Correct the sample-size claim before interpreting the analysis.

Turn 4. The analysis must reflect the real dependence and number of independent samples.

[Return to the conversation, page 113](#)

Additional case 3 / Explanations

Extended conversation

1. Coded data

Turn 2. Coded data use identifiers such as study codes; coding does not by itself make every use or transfer unrestricted.

2. secondary-use

Turn 4. Secondary-use review assesses a further research purpose beyond the initially authorized use, rather than assuming access covers every question.

3. consent scope

Turn 6. Consent scope defines the relevant uses participants agreed to and any limits that must be respected in the proposed research.

4. data-use limitations

Turn 8. Data-use limitations specify restrictions attached to the records or consent groups; combining files does not remove those restrictions.

5. data-use agreement

Turn 10. A data-use agreement records permitted handling and use between parties; it must align with the governing permissions rather than replace them.

6. withdrawal request

Turn 16. A withdrawal request requires review under the relevant consent, policy, and legal framework; its effects should not be invented or ignored.

[Return to the conversation, page 115](#)

Transfer exchange

1. credentials

Scientist: Existing access does not authorize sharing our credentials.

Turn 1. Credentials identify authorized access and must not be lent to bypass user approval.

Additional case 3 / Explanations / continued

2. process

Governance lead: Submit the collaborator through the named-user access process.

Turn 2. The collaborator needs the applicable review and authorization for their own access.

3. use

Scientist: We must also confirm that the proposed question is a permitted use.

Turn 3. User approval and permitted research purpose are related but separate requirements.

4. scope

Governance lead: Keep the data within the current authorized scope meanwhile.

Turn 4. The unresolved proposal does not expand the existing authorization while review is pending.

[Return to the conversation., page 117](#)

Find a phrase by purpose

Platform Technology and Scientific Thesis

Lead with the observation: We observed a 40% average reduction in the reporter signal.

Name the system: The data come from three independent preparations of one cell line.

Limit the breadth: Other disease systems have not yet been tested.

[Full phrase bank, page 7](#)

Assay Development and Reproducibility

Separate the levels: The within-run precision is consistent, but the day means differ.

Give the values: The means are eighty, one hundred, and one hundred twenty-five signal units.

Define the statistic: The CV describes relative spread within each run.

[Full phrase bank, page 18](#)

Biomarkers and Translational Strategy

Ask for the scope: Validated for which measurement and intended use?

State the analyte: The test measures the specified protein in plasma.

Name the range: The assessed measurement range is two to twenty research units.

[Full phrase bank, page 30](#)

Preclinical Data Packages

Name the model result: The treated group had a 20% lower mean model-endpoint value than controls.

State the groups: There were twelve treated animals and twelve controls.

Identify the tested condition: The result comes from one tested exposure.

[Full phrase bank, page 43](#)

Find a phrase by purpose / continued

CMC and Scale-Up in Biotech

State the observed scale: Both results came from one-liter runs.

Name the stage: The measured value is harvest titer, not released final quantity.

Show the arithmetic: At the same titer, two hundred liters would contain one hundred sixty grams at harvest.

[Full phrase bank, page 58](#)

IP, Freedom to Operate, and Collaboration

Identify the signed document: The confidentiality agreement is signed; the material-transfer terms are not final.

Define the activity: The proposed use is three named nonclinical bench assessments.

Separate permissions: Permission to receive information does not necessarily authorize use of the material.

[Full phrase bank, page 68](#)

Investor and Board Updates

Lead with the decision: We are asking for a bounded follow-up budget, not declaring the milestone complete.

Report the work: Four binding experiments and two functional runs are complete.

Name the criterion: The gate requires three consistent independent functional runs.

[Full phrase bank, page 82](#)

Partnering and Business Development

Acknowledge the interest: I understand that you want protection for the resources you would commit.

Define the first stage: The proposed evaluation covers T2 and T5 for six months.

Challenge the breadth: All platform applications is broader than the work currently proposed.

[Full phrase bank, page 94](#)

Vocabulary index

acceptance criterion[Lesson 02, p. 17](#)**aggregation**[Lesson 05, p. 55](#)**analytical validation**[Lesson 03, p. 28](#)**assay drift**[Lesson 02, p. 17](#)**assignment**[Lesson 06, p. 66](#)**balanced design**[Case 2, p. 109](#)**batch effect**[Case 2, p. 109](#)**between-day variation**[Lesson 02, p. 16](#)**bioavailability**[Lesson 04, p. 40](#)**biodistribution**[Lesson 04, p. 41](#)**Biological replicates**[Case 2, p. 109](#)**biomarker qualification**[Lesson 03, p. 28](#)**board ask**[Lesson 07, p. 80](#)**calibration**[Lesson 02, p. 17](#)**cell line**[Lesson 01, p. 5](#)**change control**[Lesson 05, p. 56](#)**clinical validation**[Lesson 03, p. 28](#)**Coded data**[Case 3, p. 114](#)**comparability**[Lesson 05, p. 56](#)**confounding**[Case 2, p. 109](#)**context of use**[Lesson 03, p. 28](#)**control condition**[Lesson 01, p. 5](#)**accuracy**[Lesson 02, p. 16](#)**analyte**[Lesson 03, p. 28](#)**assay development**[Lesson 02, p. 16](#)**assay interference**[Lesson 01, p. 6](#)**background IP**[Lesson 06, p. 66](#)**base case**[Lesson 07, p. 81](#)**batch record**[Lesson 05, p. 57](#)**bias**[Lesson 02, p. 16](#)**bioburden**[Lesson 05, p. 56](#)**biological replicate**[Lesson 01, p. 5](#)**biomarker**[Lesson 03, p. 28](#)**blinding**[Lesson 04, p. 40](#)**budget variance**[Lesson 07, p. 81](#)**cash runway**[Lesson 07, p. 81](#)**cell-line authentication**[Case 1, p. 104](#)**clinical utility**[Lesson 03, p. 28](#)**CMC**[Lesson 05, p. 55](#)**coefficient of variation**[Lesson 02, p. 16](#)**confidentiality obligation**[Lesson 06, p. 66](#)**consent scope**[Case 3, p. 114](#)**contingent funding**[Lesson 07, p. 81](#)**cost sharing**[Lesson 08, p. 92](#)

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References and publication notes

All cases, organizations, figures, and conversations are fictional teaching material, not transcripts. Communication practice does not replace qualified advice or current workplace procedures.

[1] Assay Guidance Manual. Basic Guidelines for Reporting Non-Clinical Data.

Background on reporting experimental conditions, types of replicates, and variation. The datasets and research conversations are original. Source checked 10 October 2026.

<https://www.ncbi.nlm.nih.gov/sites/books/NBK550206/>

[2] FDA-NIH Biomarker Working Group. BEST Resource: Validation.

Background on distinguishing analytical performance from clinical validation for an intended use. Source checked 10 October 2026.

<https://www.ncbi.nlm.nih.gov/books/NBK464453/>

[3] US Food and Drug Administration. ICH Q5E: Comparability.

Background on quality-focused comparability after manufacturing changes. No example constitutes a regulatory determination. Source checked 10 October 2026.

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q5e-comparability-biotechnologicalbiological-products-subject-changes-their-manufacturing-process>

[4] World Intellectual Property Organization. Technology Transfer Agreements.

Background on confidentiality, material transfer, licensing, and collaboration arrangements. Fictional terms are discussion examples, not model legal clauses. Source checked 10 October 2026.

<https://www.wipo.int/en/web/technology-transfer/agreements>

Companion course

The website offers the eight-lesson course and related practice. This book can be used independently. No audio access or external account is needed for its exercises.

<https://englishladder.com/efsp-biotechnology.html>

Explain the signal. Define the claim. Connect evidence to decisions.

Eight conversations connecting laboratory evidence, development decisions, and collaboration terms.

Platform Technology and Scientific Thesis

Three independent preparations provide information about variation within the tested biological system. They are not three diseases or three clinical trials. A reporter signal can support a research direction without establishing the full mechanism or proving human benefit.

Assay Development and Reproducibility

A 5% within-run coefficient of variation describes relative spread inside that run. It does not establish matching means across days or accuracy against a reference. Without supplied acceptance criteria, the exercise cannot declare the assay validated or failed.

Biomarkers and Translational Strategy

Analytical validation concerns the measurement; clinical validation concerns the proposed clinical relationship. Clinical utility asks a further question about using the result in a decision. None of these labels should be inferred solely from another label or from an attractive plot.

Preclinical Data Packages

A 20% lower model-endpoint mean is not automatically a 20% clinical benefit or a statistically established effect. State the comparison and missing uncertainty information. Randomization and blinding are distinct design features; one does not establish the other.

Phil Stilwell

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