How Many Laboratories Are Enough?

Navigating Laboratory Participation in Interlaboratory Precision Studies

The question of how many laboratories are enough is one of the first questions in interlab studies. During study design and recruitment, the question is *How many labs should we recruit?* When sign-ups are low or samples are limited, the question may become *What's the minimum recruitment need?* Then, during data analysis, laboratories may have withdrawn, or some measurements may be submitted as "not reportable" or "<LLOQ." The question may shift to *Do we have enough data sets?*

When laboratory count is limited, the number matters. It affects the information available about between-laboratory variability and the reliability of resulting repeatability and reproducibility (r&R) estimates. But the appropriate number also depends on what the study must establish, any applicable requirements or study-design guidance, the laboratory population to be represented, and the experimental design.

TL;DR

There isn't one laboratory count that is right for every interlaboratory precision study, often referred to as an "r&R study." However, there is a structured way to determine the appropriate number for a particular study: **consider four interrelated things and then plan for reality.**

Consider four things:

1. Applicable requirements and study-design guidance.
Determine what governs the study. A regulation, regulatory guidance, or contract may prescribe participant counts; standards and protocols may provide study-design guidance. For example, the harmonized IUPAC/AOAC protocol recommends at least eight laboratories submitting valid data for each material for collaborative method-performance studies, while permitting five in specified circumstances with the consequence of wider confidence intervals.[1] ISO 5725 approaches the question through the statistical design of the study rather than establishing one minimum laboratory count for every application.[2–4]

2. Laboratory population.
Determine which laboratories the resulting precision characterization is intended to represent. A study intended to characterize performance among experienced laboratories routinely using a method may require a different participant population than one intended to understand performance as the method is transferred to new users. More laboratories generally provide more information about between-laboratory variability, but additional laboratories do not improve representation simply by increasing the count.

3. Study design.
Determine how laboratories, replicates, materials, and levels will generate the precision information the study needs. Additional measurements within one laboratory and measurements from additional laboratories provide different information. Different experimental designs can therefore require different numbers of participating laboratories to produce the evidence needed.

4. Required reliability.
Decide how reliably the precision characteristic must be estimated for its intended use. A preliminary study intended to guide additional work may tolerate greater uncertainty than a study supporting a consequential safety, regulatory, or commercial decision. For a basic ISO 5725-2 design, Annex A provides a quantitative planning approach relating lab count and replication to the uncertainty of precision estimates; other designs require the corresponding planning approach.[3]

Then plan for reality:

Determine the minimum participation needed to estimate the precision characteristics with the required reliability. Then set the recruitment target high enough to meet that need while allowing for foreseeable withdrawals, missing or excluded results, and analytical limitations.

Planning this way gives the recruitment target a scientific basis before the study begins. If fewer or different data are available after testing, the same considerations help determine what precision characterization the resulting evidence can support.

Why laboratory number matters

A laboratory in an interlaboratory precision study is not simply another replicate. Within-laboratory replication and additional laboratories provide different information: replication informs repeatability; additional laboratories provide the between-laboratory information needed to estimate reproducibility.

How many laboratories participate affects how reliably that between-laboratory variability can be estimated. Precision estimates are themselves subject to uncertainty, and ISO 5725-3 relates their reliability to participant number and experimental design.[4]

Which laboratories participate affects what population the resulting estimate can represent. ISO 5725-1 treats participating laboratories as a sample of the population to which the precision characteristics are intended to apply.[2]

A note on earlier ISO 5725 guidance.

The first edition of ISO 5725-1 (1994) noted that 8–15 laboratories were commonly chosen as a practical compromise between available resources and reducing the uncertainty of precision estimates to a satisfactory level. In the current series, guidance on laboratory number has moved to ISO 5725-2, which uses an uncertainty-based planning approach rather than retaining the former general statement that 8–15 laboratories were commonly chosen.[6]

Applicable regulatory, contractual, customer, or internal requirements should be identified first. The sources in Table 1 below illustrate how widely used scientific standards and protocols approach laboratory participation.

If participation is lower than planned

Fewer laboratories than planned does not create a new minimum-count question. It creates an evidence question. Reassess the precision estimates actually obtained, the uncertainty associated with them, the laboratory population represented, and the intended use of the results. The available evidence may still support the intended precision characterization, may support a narrower or more qualified conclusion, or may be insufficient for the intended use.

Table 1. How do established sources approach laboratory participation?

Source	Context	What it tells the study designer	Nature
ISO 5725-1:2023	General principles	**Who should the laboratories represent?** Participating laboratories represent a sample of the population to which the precision characteristics are intended to apply.[2]	Principle
ISO 5725-2:2019	Basic balanced interlaboratory r&R design	**How many labs and results per lab are needed?** Annex A relates laboratory number and the number of results per laboratory to the uncertainty of precision estimates and provides equations for planning laboratory recruitment and replication.[3]	Statistical/design guidance
ISO 5725-3:2023	Intermediate precision and alternative designs	**How can study design affect the number of labs needed?** Participant number and experimental design affect the reliability of precision estimates; alternative designs can change the number of participating laboratories needed for a given level of reliability.[4]	Statistical/design guidance
Harmonized IUPAC/AOAC protocol	Collaborative method-performance studies	**How many labs are needed?** Recommends at least 8 laboratories submitting valid data for each material; permits 5 in specified cases involving specialized laboratories or very expensive equipment, with wider confidence limits when fewer laboratories participate.[1]	Study-design recommendation
IUPAC Recommendations 2021	General analytical-metrology concepts	**What affects the minimum lab number needed?** Minimum participation depends on metrological properties of the measurement procedures, including precision and analytical selectivity.[5]	General guidance

A numerical criterion only answers the question for which it was established. A laboratory count recommended for one purpose or design should not automatically be applied to another.

The number recruited may not be the number informing the result

The laboratory count relevant to a precision estimate is the number actually informing that estimate, which may be smaller than the number of laboratories originally recruited. Missing or excluded results and analytical limitations can further reduce the data available for a particular analyte, material, or level.

This is particularly important in trace analysis. Results may fall within the quantifiable range of a laboratory's method. Results below the laboratory's lower limit of quantitation (LLOQ) may instead be reported as numerical values or only as "<LLOQ" without the numerical value. These data types do not necessarily provide equivalent information, and their treatment depends on the study design and statistical procedure. When many laboratories in the study do not provide quantitative results that can inform the precision estimate at a particular level, the issue can affect both the number of laboratories informing the estimate and whether that level can support the intended precision characterization.

A quick r&R primer

s_r Repeatability standard deviation

s_R Reproducibility standard deviation

r Repeatability limit

R Reproducibility limit

In this note, "precision estimates" refers collectively to these statistics when distinguishing among them is not necessary to the discussion.

Table 2. What does this look like in real studies?

Situation	Real-world example	Participation pattern / outcome	What it shows
Complex multi-analyte studies	FDA EAM 4.7 interlaboratory validation of elemental analysis in foods[7]	**14 laboratories overall** **Above-LLOQ results** • Ni — infant formula: 8; swordfish: 4 • Pb — chocolate: 5; rice flour: 5; sunflower seeds: 2; swordfish: 2 **Study-specific acceptance criterion** • ≥8 laboratories with above-LLOQ results **Low-level results:** • Numerical below-LLOQ results were used in some sparse cases and identified separately.	The number of labs informing a precision result can differ by analyte and matrix. The study's overall lab count does not establish how much quantitative evidence supports each result.
Varied implementations	PFAS interlaboratory validation in foods of plant origin[8]	**4 laboratories; 7 analytical setups** Same instrument class in different laboratories • trueness error – no significant difference in one comparison • RSD – significant difference • Authors identified a laboratory-dependent implementation effect	Labs are not necessarily interchangeable sources of information. The observed lab-dependent effect illustrates why participant selection should reflect the intended laboratory population and study purpose.

The laboratory count relevant to a conclusion may therefore belong to the particular estimate, not to the study as a whole.

Table 3. How do I determine the appropriate participation for my study?

Step	Ask	Consider
1. Applicable requirements and study-design guidance	What governs or guides this study?	• Regulation or regulatory guidance • Standard or protocol • Contract/customer requirement • Internal requirement
2. Laboratory population	Which laboratory population must the precision characterization represent?	• Routine users vs. new adopters • Experience level • Technologies or implementations • Relevant laboratory types
3. Study design	How will laboratories, replicates, materials, and levels generate the needed precision information?	• Laboratories vs. replicates • Number/range of materials or levels • Basic vs. alternative design
4. Required reliability	How reliably must the precision characteristic be estimated for its intended use?	• Preliminary vs. definitive use • Consequence of the decision • Required uncertainty of the estimate
Plan for reality	What recruitment target is needed to achieve the required reliability, account for foreseeable data loss, and execute the study as designed?	• Recruitment feasibility • Availability of appropriate laboratories • Samples/materials • Time/resources • Withdrawals • Missing/excluded results • Analytical limitations

Before recruitment, confirm that the required participation can realistically be achieved with the appropriate laboratories, samples, time, and resources. If it cannot, reconsider the design and intended conclusion before proceeding. Depending on the purpose, that may mean changing the design or recruiting targets, obtaining other supporting evidence, accepting greater uncertainty in the estimate where scientifically appropriate, narrowing the conclusion to what the available evidence supports, or determining that the intended precision characterization is not supported. **Keep in mind, a practical constraint does not remove its statistical consequence.**

For an ISO 5725-2-type study, Annex A provides a quantitative approach for planning laboratory recruitment and replication in relation to the uncertainty of the precision estimates.

Before and After the Study

Before recruitment, work through the four steps and document the basis for the participation needed. Set the recruitment target high enough to account for foreseeable data loss, and confirm that the study can realistically be executed as designed.

After testing, reassess the evidence actually available. If participation differs from what was planned—or differs by analyte, material, or level—determine what precision characterization those data can support.

References

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