

# 503Pharma Group Stability Study Program

Answers to common questions from 503Pharma members about the founding member stability program, including study rights, membership value, lab requirements, MFR matching, and study outcomes.

<b>\$4,000/year</b> Founding member fee	<b>3+ studies</b> At least three Year 1 studies planned
<b>\$10K-\$20K</b> Typical individual study cost	<b>20 slots</b> Limited founding membership

**Important:** This FAQ is informational and does not replace your pharmacy's own regulatory, legal, or quality review. Each pharmacy remains responsible for confirming that its formula, process, documentation, and use of any stability data are appropriate for its operations and jurisdiction.

## What does the \$4,000 founding membership include?

The founding membership includes access to all stability studies released during the member's active membership year. There is no added per-compound charge for studies released during that year. The program is designed to be cost-effective: an individual study can often cost \$10,000-\$20,000, while founding members get access to at least three Year 1 studies for \$4,000 total.

## If we do not renew, can we keep using completed studies?

Yes. Participating pharmacies retain the right to reference stability studies, data, COAs, and BUD documentation completed during their active membership term. If a pharmacy does not renew, it would lose access to new studies and compounds added after the membership lapses.

## What happens if 503Pharma changes ownership or ceases operations?

The intent is that member pharmacies retain the right to use studies completed during their active membership term, even if 503Pharma were later dissolved, acquired, or otherwise changed.

## How closely does our pharmacy need to match the MFR?

The most important items to match are the formulation and container-closure system: same API, excipients, concentrations, pH, vial type, stopper, and seal. Process-level differences may be acceptable if the final product meets the same release specifications, including sterility, potency, particulates, and endotoxin. Each study packet will include applicability criteria so members can see what must match exactly and where there is flexibility.

## Are members required to use a specific laboratory for routine testing?

No. The program will use accredited laboratory partners for the group studies, but members are not required to use those same partners for their own routine release testing. To rely on a study, the member pharmacy's formulation and relevant quality specifications must match the study parameters.

## Which lab is being used for the studies?

Laboratory partnerships and final study designs are being finalized. The final study packet for each compound will identify the laboratory, study design, testing approach, storage conditions, pull dates, and documentation package.

## What counts as a successful study?

The goal of each study is to establish the longest scientifically supportable BUD for the tested formulation. If a study targets a 90-day BUD but the data supports a 45-day BUD, that can still be a valuable, validated extension beyond default USP <797> limits. The study result is driven by the data, not by a guaranteed target.

### **Are refunds available if a study result is shorter than expected?**

Refunds are not based on study outcome. Members are funding the scientific work and shared data package, not purchasing a guaranteed BUD. However, if the minimum enrollment threshold is not met and the program does not launch, members receive a full refund.

### **What is the minimum enrollment threshold?**

The program requires at least 10 enrolled pharmacies to launch. If that minimum is not met, enrollment payments are refunded. Founding membership is limited to 20 pharmacies.

### **How are API suitability and regulatory uncertainty handled?**

503Pharma is sequencing studies based on regulatory clarity, member demand, and the availability of compliant API sources. The program will not ask members to rely on stability work for a formula or API source that is not appropriate for their pharmacy. Each pharmacy should still complete its own sourcing, documentation, and regulatory review before using any study data.

### **Will GLP-1s or other peptides be included?**

Member demand will help shape the study pipeline. GLP-1 related compounds and other peptides are being considered, including semaglutide, tirzepatide, and additional peptide formulas, as regulatory clarity, API availability, and member demand support them.

### **What documentation will members receive?**

Members should expect a study packet that includes the study design, tested formulation parameters, applicability criteria, data, COAs, and BUD-support documentation for completed studies. The exact contents may vary by compound and final study design.

### **Will studies include shipping or storage condition considerations?**

Where scientifically appropriate, the study design may include multiple storage conditions or shipping-relevant data points. Final storage conditions, pull dates, and testing approach will be specified in the study packet for each compound.

### **How do we reserve a founding member slot?**

Reply to the 503Pharma enrollment email or contact [info@503pharma.com](mailto:info@503pharma.com) and indicate that your pharmacy wants to reserve a founding member slot. Slots are limited and enrollment is targeted to close July 15, 2026.

Last updated June 29, 2026. Based on 503Pharma member questions received during the week of June 22, 2026.