CERTARA

Fact sheet

Expedited Pharmacometrics Regulatory Submissions

Overview

Pharmacometrics (PMx) analyses are essential to dose justification, efficacy and safety evaluation, and benefit–risk decisions in NDA/BLA/MAA submissions. However, PMx activities are traditionally one of the longest and most sequential components of the filing process.

Certara removes this bottleneck by delivering complete, compliant PMx submission packages in just 4 to 6 weeks instead of the typical 8 to 12, without compromising rigor, accuracy, or alignment with regulatory expectations. The team of over 120 scientists has completed more than 800 high quality, submission ready PMx analyses to date.

The challenge

Following final database lock, PMx submissions typically require multiple dependent steps, including:

- Population PK and exposure–response analyses
- Comprehensive simulations using Phase 1–3 clinical trial data to support dose regimen justification
- Full pharmacometrics analysis reports
- CTD Module 2 and 5 components formatted for direct inclusion in the eCTD

Because these activities are usually completed sequentially, they often drive 8–12 weeks of additional timeline and place PMx on the critical path to filing.

How Certara delivers 4–6-week PMx submission packages

To eliminate sequential bottlenecks while maintaining regulatory completeness, Certara applies a purpose-built accelerated submissions model:

Strategy	Impact
Detailed project plan aligned to submission timeline	Reduces ambiguity and prevents rework
Early front-loading of dataset programming, model updates, mock reports and CTD content	Allows activities to begin before database lock
Parallelization of critical workstreams with additional expert resources	Removes traditional sequential dependencies
Global team distribution (USA / Europe / APAC)	Enables 24-hour progress without burdening sponsor teams
Standard templates and regulatory-grade scripts	Ensures consistency, accuracy, and traceability
High-touch communication cadence	Keeps decisions timely and projects on track

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Results

By combining these strategies, Certara consistently delivers:

- **Full PMx submission packages in 4–6 weeks (vs. 8–12 weeks traditionally)**

Sponsors gain:

- Full quality and compliance — no shortcuts
- Confidence that PMx will not delay filing
- Clear visibility and control across the submission timeline

Why sponsors rely on Certara

- Largest global PMx submissions team with unmatched regulatory experience
- Proven track record supporting hundreds of NDA/BLA/MAA submissions
- Deep familiarity with agency expectations and preferred formats
- End-to-end support from dataset programming through CTD integration

Start early. Submit faster. De-risk the path to approval.

Whether for a traditional submission, rolling submission, accelerated approval, or a late-phase program under pressure, Certara provides scalable expertise to keep your filing on track and prevent PMx from becoming the critical-path delay.

Start early and finish on time with expedited PMx that supports your submission timeline.

Explore Certara's Pharmacometrics Consulting Services

About Certara

Certara accelerates medicines using proprietary biosimulation software, technology and services to transform traditional drug discovery and development. Its clients include more than 2,600 biopharmaceutical companies, academic institutions and regulatory agencies across 70 countries.
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