Ready Set Submit: The Dossier Support You Need to Get Your NDA, MAA, BLA or PMA Done

Highlights in the past 5 years:

12+ FULL NDA SUBMISSIONS | **60+** CDISC CONVERSIONS | **20** ISS/ISE PREPS | **9** FDA/EMA REPRESENTATIONS

Count on Us to Meet Your Dossier Submission Deadlines

The dossier submission always has a tight timeline and much riding on it – promises to investors, marketing campaigns poised to launch, patent protection status risk, and in some countries, fixed time points to meet the requirements for inclusion in the national formulary drug lists. Hitting the defined timeline is critical and is the ultimate measure of clinical drug development success.

The biggest challenge? Preparing the NDA, BLA, MAA, or PMA always takes longer than expected, thus should be started earlier than most drug developers anticipate. Sponsors often discover this process takes more people with programming, analysis, and writing expertise than available within their company or with their current trial partner. Further, additional regulatory guidance may be necessary since teams may not have the most up-to-date knowledge of the changes in the regulatory landscape or may not be familiar with the regulatory agency with which they are filing, especially if this is the first time working with that particular regulatory body.

Handling All Submission Parts Expertly: Ready Set Submit

When you need help, call Synteract. Our Ready Set Submit bundled service offering will help you bring it all together to complete your submission on time. We can work with you across all these needs, or just lend support on individual aspects along the preparation path. We have the regulatory knowledge, the statistical expertise, the ability to reconstruct and compile the legacy data, the programming capabilities, and the medical writing expertise you need to bring peace of mind to your clinical trial team and investors alike.

Ready Set Submit services include:

- Integrated analysis plans
- Data pooling
- Dictionary coding and recoding for consistency
- ISS and ISE creation
- NDA, BLA, MAA writing, compilation and submission
- eCTD production, including preparation, bookmarking and hyperlinking as well as submission through electronic gateways
- Statistical consultation and representation
- Strategic guidance and support for FDA/EMA meetings

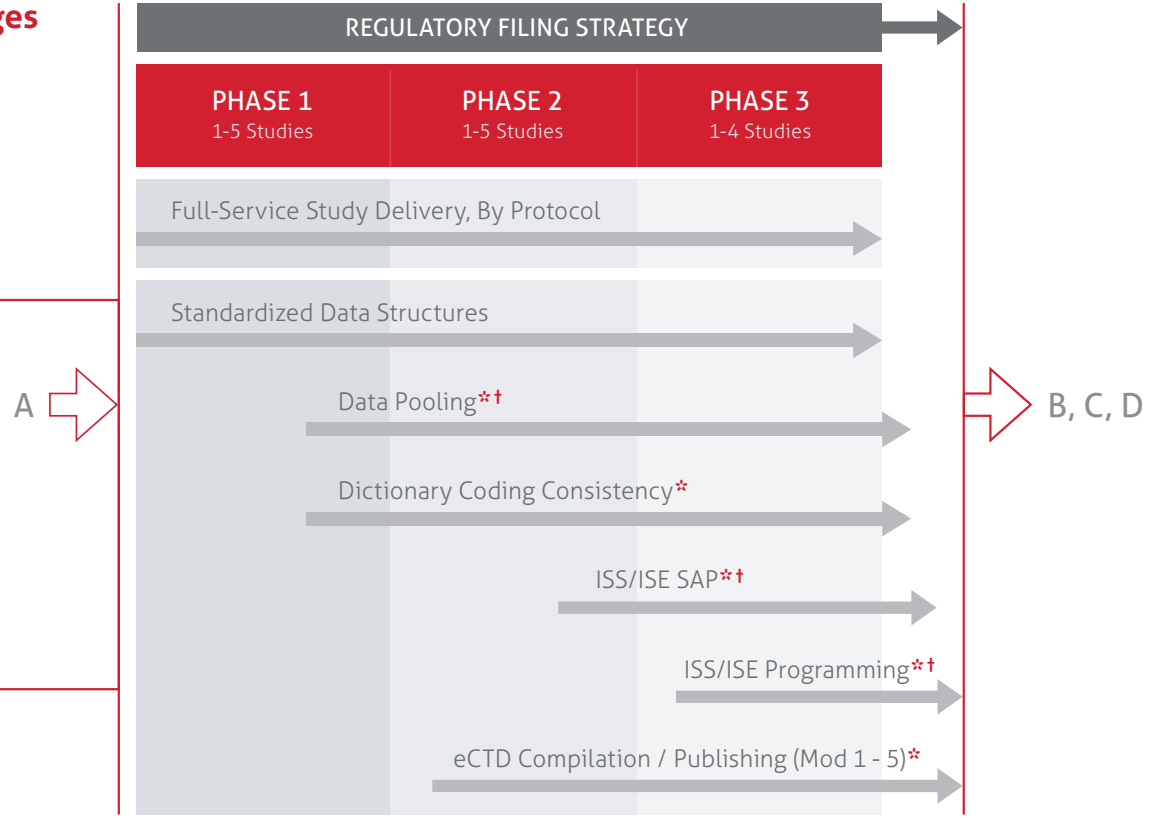
Ready Set Submit Helps with Your Biggest Challenges

Even when your trials work perfectly, taking new products successfully through submission and approval can be a challenging and lengthy process. Contact us early to get the support you need from our highly responsive and experienced regulatory affairs, biostatistics, medical writing, and programming experts.

A: Post IND Submission
B: NDA, BLA, MAA Submission
C: Post-Submission Meetings During Review
D: Approval by Agency

✲ Often start late, so jammed on critical path for submission

† Requires 5-30 FTEs; volume and timeline dependent



About Synteract:

With employees across 21 countries, Synteract is an innovative, full-service CRO supporting biopharma companies across all phases of drug development to help bring new medicines to market. Synteract has conducted 4,000 studies on six continents and in more than 60 countries, working with more than 26,000 investigative sites and 750,000 patients. It has contributed to more than 240 product approvals. Synteract offers a notable depth of therapeutic expertise in oncology, dermatology, and neuro degenerative indications, as well as rare and orphan, pediatric, and immunotherapy studies.

For more information on how we can support your clinical trial, please visit www.synteract.com/Services/Dossier-Submission or ContactUs@synteract.com.

Synteract.com

BRINGING CLINICAL TRIALS TO LIFE™