



# READY SET SUBMIT:

the dossier support you need  
to get your NDA, MAA, BLA  
or PMA done

In the past 5 years, Synteract has conducted:

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

Call us to see how Synteract's Ready Set Submit services can help you!

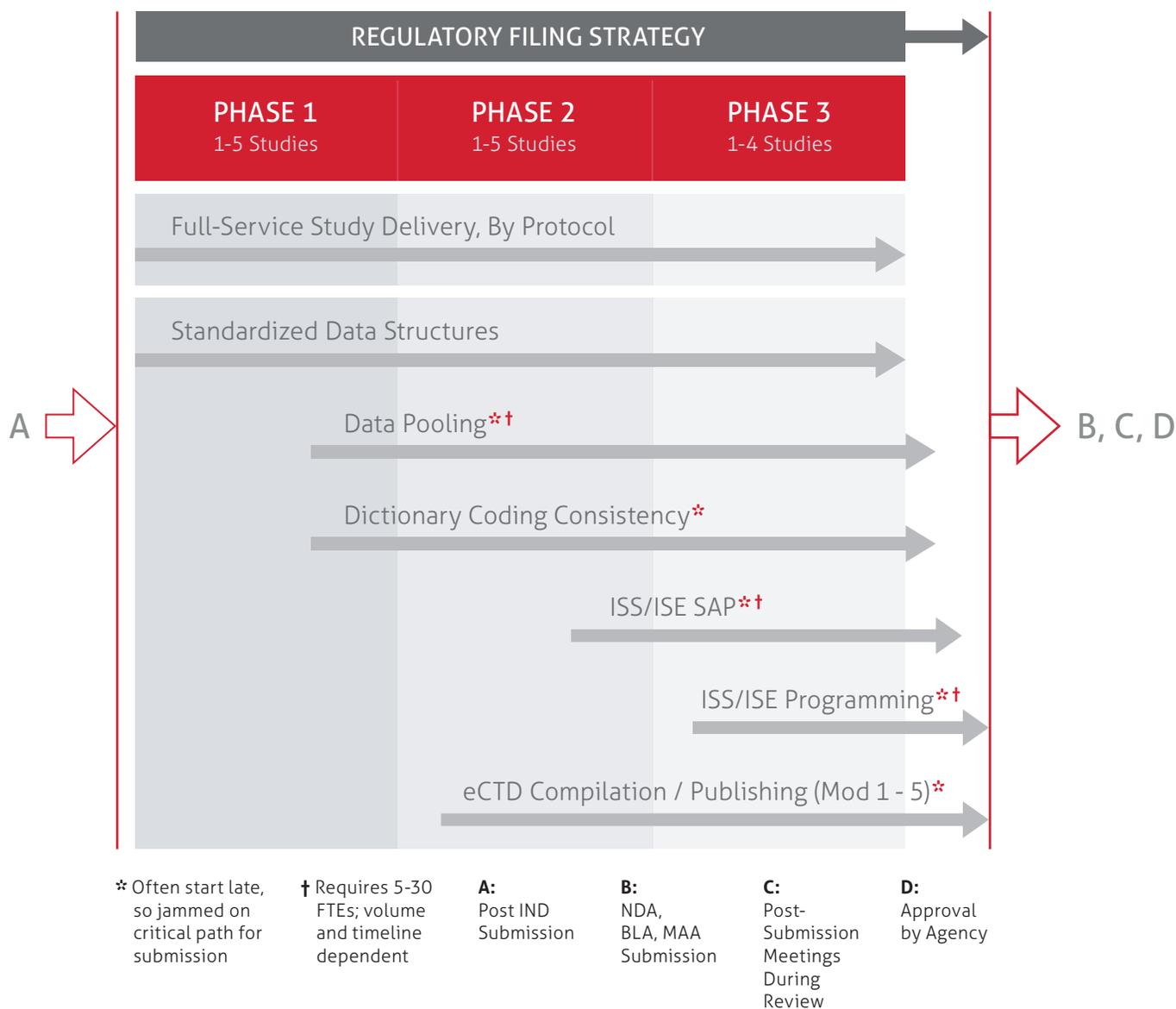


## A True Team Effort

The multi-disciplinary and cross-functional team that provides Syneract's Ready Set Submit service consists of a team of experts with experience in biostatistics, CDISC and programming, medical coding, medical writing, regulatory and project management. This team works together seamlessly, led by a submission project manager who is skilled at integrating and orchestrating these multi-pronged efforts that are unique to dossier preparation and submission. The sponsor benefits from working through one experienced point of contact yet accessing the expertise of many.

## 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.



[Syneract.com](http://Syneract.com)

BRINGING CLINICAL TRIALS TO LIFE™