

Standardized Data (SDTM)

We provide regulatory-compliant data formatting, CDISC SDTM alignment, and seamless system integration to support successful submissions.

Analysis Data (ADaM)

We deliver accurate data structuring, regulatoryready ADaM datasets, and efficient SDTM-to-ADaM mapping.

Analysis Outputs (TFLs)

We deliver high-quality tables, figures, and listings aligned with analysis plans and ready for submission.

Regulatory Submissions & Data Integration

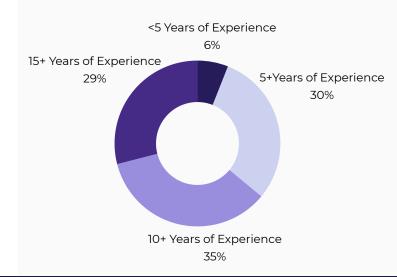
We support regulatory reviews with ISS/ISE, legacy CDISC conversions, quality checks, and FDA/EMA strategic submission input.

Regulatory Submission Excellence

Submissions to date

Rejections or technical concerns

Our Team



WHY BIOFORUM?

Submissions Experience

Proven track record delivering validated, compliant outputs for global regulatory submissions.

Adapting to evolving demands

Setting clear timelines, conducting reviews, and staying prepared for ad-hoc requests.

Global Support

Our distributed team supports all time zones, ensuring seamless collaboration and continuous progress.

