

Interim Study Monitoring: Available on a Per-Study or Monthly Recurring Basis

Interim Study Monitoring gives Sponsor access to all generated study data in an analyzable format for visualization and derivation of insights to make data-driven decisions mid-study and in near-real time.

This is enabled by PointCross' Xbiom™ data analysis platform coupled with our Data Concierge Service which is primarily responsible for study loading and integration with the constellation of your CRO network / specialty labs.

Xbiom™ is a SaaS provisioned analysis platform and study repository that securely warehouses and indexes Sponsor's study data for easy search and cross-study analysis. Sponsors generate annotated Tables, Listings & Figures with the click of a button, and collaborate across departments with access to the same view of data rather than having to perform data wrangling or make frequent cross-departmental asks.

Xbiom serves as an indexed, searchable data warehouse and study repository for many of our customers, and is also flexible to help Sponsors monitor single or multiple studies per month.

The following pricing table reflects the standard Xbiom™ Single Instance, Multi-Tenant, SaaS offering with an average of 3 studies to be monitored in a given month. For dedicated hosting or on-premise options, please let us know at ask@pointcross.com.

Interim Study Monitoring Offers	Monthly Price
A) Xbiom Platform	\$ 5000 / month
<i>a. Xbiom Nonclinical Insights Module</i>	<i>Unlimited # of users</i>
B) Data Concierge Service	\$ 7500 / month
<i>a. Interim Study Monitoring</i>	
<i>- Loading of Interim data into Xbiom</i>	<i>3 Ongoing studies per month</i>
<i>- PointCross Integration with CRO/ Labs for study/assay data</i>	<i>Unlimited # of CROs or Lab integrations for collecting generated study data</i>
<i>b. # of completed studies in SEND-like format: Loaded into Xbiom Insights Module</i>	<i>3 completed SEND-like studies per month</i>
C) Additional Study Uploads	Priced per study per month
<i>a. Interim Study Monitoring</i>	
<i>- Additional Study for Interim Monitoring & Analysis</i>	<i>\$ 2500 per study</i>
<i>b. Loading of additional completed studies in SEND-like format</i>	<i>\$ 1000 per study</i>

<i>c. Loading of additional completed studies in Non-SEND, such as PDF Study Report being only source available</i>	\$ 4000 per study <i>(eTransafe Consortium agreement pricing)</i>
D) Submission ready SEND package derived from Interim study data and reconciled with final study report	40-50% Discounted SEND generation cost (each study individually quoted against indicative pricing sheet)

For our Data Concierge customers, a weekly Data Standardization, Observations, and Assumptions Report (DSOAR) is made available that serve as a reference document outlining corrections that have been made on the interim datasets (trial design issues, time-points, and other inconsistencies) in order to make them analysis ready.

The Data Concierge Service can be turned “on and off” depending on whether an ongoing study needs interim monitoring and is available on a per-month basis, allowing you flexibility for when there is a surge of study volume that requires standardization and analysis.

Additional Study Upload:

Our standard biotech pricing provides for 3 interim studies to be ingested in Xbiom per month. Any number of ongoing studies can be added in a given month, and legacy studies can be loaded into Xbiom including those not in SEND format and without source electronic data (i.e. if you only have the PDF Study Report). With completed studies, PointCross’ Data Concierge team load SEND, additional SEND-like, Xbiom for a nominal fee on a per study basis. Volume discounts are available for customers with 10+ studies.

SEND Services for Interim Study Monitoring: Lower Cost, Faster Turnaround

For Interim Study Monitoring customers looking to file a submission, PointCross offers its industry-leading SEND Data Standardization service, and is able to offer up to a 60% discount on SEND data package generation (including the data in XPT format, define.xml and define.pdf, nSDRG, validation reports). Click here for PointCross’ SEND and SEND-ASSURE data quality services. (<https://pointcrosslifesciences.com/send-services/>)

Up and Running in less than 1 Business Day

PointCross can establish a Sponsor-specific business base of Xbiom, integrate with your study CRO and specialty labs for raw study data to be loaded into a secured Virtual Data Room, and proceed to transform the as-collected data (including LIMS extracts) into an analysis-ready and visualization-friendly format within 24 hours.

Further questions? Keen to get started?
 Contact us today for more information and a demo.

We’re here for you: ask@pointcross.com