

Translational Studies Data Tiers

Data Tier	Data Type	Definition	How Provided	Timing	Contracting
Tier 1 Provided for all studies	Summary Report	Summarized report of data. Would include graphs/tables/visuals/etc., any statistical analysis, conclusions, and methods. All analyses performed should be addressed, irrespective of apparent significance of findings, or potential publication plans for the data.	Via standard report template (in development) – can be through field contact, SLRM contact, or upload into Visiontracker	Updates on study progress should be provided as part of the routine IIS quarterly status request. Full tier 1 data (all analyzes completed), must be provided upon study completion as per data sharing schedule.	Provided as part of standard contracting terms.
Tier 2 Provided upon Company's request, contingent upon internal review of Tier 1 data	Analyzed Data	Any data that is utilized to generate graphs/tables/visuals/etc. presented in Summarized Data (Tier 1), or any of the statistical analyses and conclusions arising out of that data.	Via Company specified transfer platform; format and nomenclature for data upload will be provided by Company	Within a negotiated time-frame as per the data sharing schedule in the agreement.	Provided as part of standard contracting terms, though details may vary from site to site.
Tier 3 Provided upon Company's request, contingent upon internal review of Tier 2 data	Raw Data	Data obtained directly from machine outputs used as a basis to generate the analyzed data for graphs/etc.	Via Company specified transfer platform; format and nomenclature for data upload will be provided by Company	Within a negotiated time-frame as per the data sharing schedule.	Provided as part of standard contracting terms, though details may vary from site to site.