

Study Optimizer

DESCRIPTION OF SERVICES

<b>Study Description:</b>	<p><i>Studies are defined as a clinical trial study (interventional) or proposal developed for one client, by one or more investigators, with one specific research plan and protocol number identified by Client, which describes the objective of the clinical trial for the client, including therapeutic area or drug of interest.</i></p>
<b>Background:</b>	<p>IQVIA is the provider of multiple database systems to assist in the administration of clinical studies, including StudyOptimizer software, Data Virtualization software, the GrantPlan system (“GrantPlan”), the Enrolment Benchmarks tool, collectively referred to in this SOW as the “Database Systems.” Subscribers to the Database Systems pay a yearly subscription fee to IQVIA for use of each Database System and provide IQVIA with information to be included in databases for each of the Database Systems.</p>
<b>Description of Database System:</b>	<p><b><u>StudyOptimizer</u></b> A web-based solution that enables life sciences companies to deliver clinical trials on time and on budget by automating the process of planning and tracking patient enrollment.</p> <p><b><u>Data Virtualization / Enrollment Benchmarks</u></b> An industry benchmark available as an option within StudyOptimizer which aggregates industry past performance data to allow for more realistic planning and forecasting for similar studies.</p>
<b>Client Data Criteria</b>	<p>Client shall provide the data required for use of each of the Licensed Databases (“Client Data”), as follows:</p> <p><b><u>Data elements for StudyOptimizer:</u></b></p> <ul style="list-style-type: none"> <li>• Study Names will be eliminated</li> <li>• Study IDs will be randomly substituted with generic identifiers such as X1234, Y1245, and so forth</li> <li>• Countries and regions will be organized according to UN standard, which information is only provided to the country-level and no lower</li> <li>• Indications and therapy areas will be normalized to a standard set of categories, such as Diabetes, Cardiovascular, Endocrinology, etc.</li> <li>• Personally identifiable information will be eliminated</li> <li>• Investigator information will be eliminated</li> <li>• Component names and project names will be eliminated</li> </ul> <p>Analyzed Data (as defined in Schedule 2) will include historical metrics which will be aggregated by generic therapy area, generic indications, phase, number of subjects, and number of sites.</p>
<b>Timeline and Submission of Client Data</b>	<p><b><u>Timeline and Submission of Client Data for all Studies:</u></b></p> <ul style="list-style-type: none"> <li>• For all studies/trials, first collection received within three months of signature</li> <li>• Time table for further collections established: monthly, quarterly, etc., at kickoff</li> <li>• Client may send link to a contracts database portal/SFTP, IQVIA uploads the data</li> <li>• Client may send to secure IQVIA email address.</li> <li>• Client may use shared file repository</li> </ul>
<b>Service Plan/Training</b>	<p><b>TRAINING</b></p> <p><b>StudyOptimizer eLearning</b> - Accessible through IQVIA Learning Management System (eLearning)</p>

## **IMPLEMENTATION SERVICES**

IQVIA will provide the following Services to implement the Licensed Software in the IQVIA Hosted Environment and train Client's users to use the Licensed Software for the fees set forth in an applicable SOW.

IQVIA's Implementation Services include:

- Client Management to drive the implementation and rollout project
- Setup and configuration of the hosted environment
- Installation and configuration of each Licensed Software in the hosted environment; configurations based on standard selections provided by IQVIA, such as algorithm settings, labels, etc. Does not include customization of the application.
- Support of Client with completing data integration for applicable products from a single source of data files to the applicable Licensed Software
- Establishing a data transfer mechanism, as necessary (e.g., sftp, site-to-site VPN)
- Application of one (1) upgrade per year, which includes release notes, upgraded documentation, online help and upgraded data mapping, if required

### Product Education Services

- ✓ Provide up to two (2) instructor-led training sessions per year delivered via online tools or in person for up to 12 users. Note: Travel fees related to training (and all other implementation and support services) are billed separately.
- ✓ Provide a soft copy of training materials

Additional training such as eLearning and additional instructor-led training sessions are not included but available at additional cost and shall not be provided unless all terms including fees are agreed to by both Parties in writing. Travel fees related to training (and all other implementation and support services) are billed separately.