GDSP statement of work (SOW)

Document goal: Ensure the right business and scientific questions are formulated, and the right analyses are designed to address these questions, and assess necessary resources identified to plan and execute plans.

Output: a brief written description of the questions to be addressed, the activities to address them and who was involved in this assessment. GDSP SOW should be stored on a **knowledge management** system, with the location of the document captured in a **tracker**.

Revision tracking: The GDSP SOW should be maintained to capture major changes in project scope during execution and completion. A change log is available to capture this information.

PROJECT INFORMATION

Project Title	*Provide a descriptive project title.*
Project code / identifier (if applicable)	*Add the project code or identifier in here if one exists. This will help with retrieval of the project materials.*
Project requestor / sponsor (if applicable)	*Add details of the requestor i.e. principal investigator, business unit, etc.*
GxP applicability?	*Indicate if this work is purely exploratory (and for internal purposes only) or if the project outcomes could be subject to regulatory interactions, part of a submission to a health authority, to a scientific publication, etc. The purpose is to help discussion and planning around potential verification and validation activities, and especially to avoid rework later.*
Project keywords	*Add keywords to help with retrieval of the project.*

PURPOSE & BACKGROUND

Provide an informal summary of the scientific/business context, and what is known about the situation at the beginning of the project. Point out the value added, including the scientific and business impact for your organization, with a clear business justification for why the project is needed? Also, provide a rationale in terms of what is already known about the problem and what gaps exist (i.e. why this project is required). It may be helpful to answer the following questions when filling out this section:

- *What problem is this project solving?*
- *How do we know this is a real problem and worth solving?*

Capture the details of any background research performed such as project identifiers or links to useful resources. It is useful to capture references to previous relevant projects, or similar work performed, to ensure existing materials and resources are utilized, as well as connecting projects to support future knowledge management and discovery.

OBJECTIVES

Describe the primary objective, from a business or scientific perspective. In addition to the primary objective (i.e., key scientific question of interest), there are typically other related questions that may be of interest address; the

primary objective or question is potentially just one of several to support the project purpose and addressing the scientific or business problem. ***Capture what is known****.*

OUTCOME(S)

Describe the criteria for a successful or useful outcome to the project from the business/scientific point of view. It might be useful to attempt to answer the question: How do we know if we have solved this problem? At the scoping phase this information might be quite specific and able to be measured objectively or it might be general and subjective. In the latter case, it should be indicated.

Also specify the format of the **expected deliverables and project artifacts** that support the outcome e.g., *Final Presentation(s), Technical Report, Scientific publication, Code Repository, Data sets, ...*

MATERIALS AND METHODS

List out the available materials and resources such as data sources, platforms, analysis tools and other resources that may be required to achieve the investigation goal(s). Provide hyperlinks to repositories/documentation used in your organization or created by the project (e.g. your organization's computing environment, document management system for regulated documents, collaborative tools such as SharePoint, one drive, drop box, google drive, a knowledge management system...). This is essential to capture the single source of truth for the project, to ensure that project information can be retrieved, as well as ***enable the repeatability and reproducibility of the project****, especially if an update, re-run, or query about specific analyses are requested. To assist knowledge management and reuse of materials and findings, review, and update key information such as links to project artifacts at closure.*

Also list out what potential tasks and activities need to be taken to achieve the goals and objectives of the project.

PROJECT GOVERNANCE

PROJECT TEAM & CONTRIBUTORS

List who are the people involved in this project. Include any stakeholders or advisors.

TIMELINES & MILESTONES

Provide a high-level indication of the timelines. This may be a rough indication at the beginning, which can be refined later.

CHANGE LOG/HISTORY

Capture changes to the SOW due to major project scope changes, relevant new information or e.g. updating of links to repositories and documentation. Also revisit this section at the end of the project when updating the SOW template. Note: this can also be managed through version control if the template uses a simple txt or markdown format.

Version	Reason for Change	Summary of Changes
<3.0> Current <Do not provide date>	Additional data available, new timeline	Content Change(s): •
<2.0> <Effective date> <e.g. 18-Aug-2018>	Project Organization, Change in GxP classification	Content Change(s): •
<1.0> <Effective date> <e.g. 14-May-2017>	Scope increase	Content Change(s): •