Novartis Third Party Management – Frequently Asked Questions

1. What is Primary Data?

Primary Data are all facts, figures and statistics collected together for reference or analysis. It includes all original Records and true copies, including Raw Data and Metadata and all subsequent transformations and reports of these data, that are generated or recorded at the time of the activity and allow full and complete reconstruction and evaluation of the activity.

2. When is non-GxP Data relevant to Quality of Health Authority Submission?

Activities may be relevant to Quality of Health Authority submission if the data that is generated as part of the activity includes preclinical/clinical safety data and/or is submitted to Health Authority as part of Clinical Trial Applications, Investigational New Drug (IND) submissions, Marketing Authorization Applications, or Post-Approval Safety Data

3. What suppliers can I select for my request if: *"The activity will generate Primary Data and is relevant to Quality of Health Authority Submission BUT is out of scope of GxP regulations."*?

For this type of request only EQIPD (Enhancing Quality in Pre-clinical Data) and Biomarkers (BMX) badged suppliers can be selected. These suppliers have been qualified for the activity impact class described in question 2.

Example of a supplier badged for both EQIPD and BMX:

If your preferred supplier is not yet EQIPD and/or BMX badged, you can request that the supplier completes the EQIPD Request for Information (RFI) by providing this link and/or the BMX RFI by providing this link via the request message functionality. Once the supplier has submitted these RFIs, the supplier can be reviewed by the responsible Qualification team in Novartis.

Alternatively, you can contact Sara Wagner Valladolid (sara.valladolid@scientist.com), the Scientist.com Biomarkers Category Director, to follow up with the supplier on your behalf.

4. What is the SOW Approval Process if: "*The activity will generate Primary Data and is relevant to Quality of Health Authority Submission BUT is out of scope of GxP regulations.*"?

If the suppliers are EQIPD and BMX badged, no further action is needed.

If the suppliers were not EQIPD and/or BMX badged, they will need to complete the EQIPD and BMX RFIs as described in question 3 and qualify under Novartis SOP-8114992.

- Once the EQIPD and BMX RFIs are submitted and the supplier is qualified, the supplier will be badged within the Novartis Creative Marketplace.
- The SOW can then be approved.
    - If the activity is led by NIBR TM, Novartis will also need to approve the SOW.

5. What are the Biomarkers and the EQIPD RFIs?

The RFIs are virtual pre-assessments that allow suppliers to share key information with clients in an easily digestible and structured manner, highlight their capabilities, and increase their visibility.

- The EQIPD RFI has been developed in partnership with EQIPD (Enhancing Quality in Pre-clinical Data), an international consortium formed to define and improve data quality within preclinical research. The information provided in this RFI helps Novartis to assess suppliers Quality and Compliance procedures and ability to ensure Data Integrity for the data generated as part of the activity.
- The Biomarkers RFI enables suppliers to communicate critical compliance information and technical capabilities to Novartis.

Both RFIs enable suppliers to provide information to Novartis (and other clients) proactively, in a single process, thus reducing costs, resources, and time. RFI responses are critical to enable Novartis qualification teams to assess critical quality and compliance elements of the supplier and are visible to approved stakeholders within Novartis, ensuring full alignment with Novartis Third Party Management processes and requirements.

6. Why does the Third Party I want to work with have to be qualified?

The Qualification process ensures that identified Third Parties undergo appropriate risk-based qualification measures prior to carrying out contracted activities. Third-Party Qualification activities are intended to understand any Technical/Quality Risk that Novartis will assume and how the Technical/Quality Risk will be mitigated. Only an approved Third Party can be used for services and activities sponsored by or in collaboration with Novartis.