Policy for Access to Residual Biological Samples and Data in the ALTTO and NeoALTTO Studies ("Policy")

Protocol Numbers:	ALTTO: BIG 2-06/N06D/EGF106708 Neo-ALTTO: BIG 1-06/EGF106903
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1. Introduction

GlaxoSmithKline Research and Development Limited ("**GSK**"), Breast International Group – aisbl ("**BIG**") and Institut Jules Bordet ("**IJB**" and previously IJB/BrEAST) entered into a Clinical Trials Agreement with an effective date of 19 April 2007 which was subsequently amended by various amendments (the "**CTA**"). The CTA was assigned from GSK to Novartis Pharma AG (**"Novartis"**) effective as of 30 November 2015.

Unless otherwise defined below, all capitalized terms in this Policy shall have the meanings as defined in Appendix 6 - Definitions.

Within the framework of the ALTTO and NeoALTTO studies, originally sponsored by GSK and now sponsored by Novartis, and conducted under the auspices of BIG and IJB, Data and Residual Biological Samples were collected, stored and later made available to carry out Follow-on Studies, for the purpose of correlative science research. The Alliance for Clinical Trials in Oncology (**"Alliance**") (previously North Central Cancer Treatment Group ("**NCCTG**")) is a partner for the ALTTO study and SOLTI is a partner for the Neo-ALTTO study. The Biological Samples and Data are available for analyses as outlined in the Studies' Protocols, as well as for new, independently-funded research projects (conducted outside the Studies' Protocols, using Residual Biological Samples and/or Data,) that may be proposed by investigators participating in the Studies and by the wider scientific community, hereinafter referred to as "**Research Project Proposal(s)**"or "RP Proposals" (RP Proposal(s)).

A strict, fair and scientific review process of RP Proposals is set up to ensure precious Residual Biological Samples and Data collected in the Studies are accessed appropriately. A distinction is made between RP Proposals requiring access to Residual Biological Samples (with/without Data) and RP Proposals requiring access to Data only (without Residual Biological Samples). This Policy provides the guidelines for the review and approval of all RP Proposals.

The term researcher or investigator used in this policy refers to any person, or legal entity which submits a RP Proposal that needs to be approved by the Steering Committee (SC), and receives the Data and/or residual Biological Samples in order to conduct its RP.

This Policy does NOT cover translational research analyses that are already part of the Studies' Protocols and/or Sub-Study.

2. General Principles

2.1 Research Project or Follow-on Study

"Research Project" or "Follow-on Study" refer to studies conducted outside the Study Protocols, using Data and/or Residual Biological Samples as specifically i) approved by the SC when it concerns Data only and ii) allowed by the TRANSALTTO Committee (TrAC) and endorsed by the SC when it concerns Data and Residual Biological Samples, including for example translational research studies.

2.2 Residual Biological Samples

"Residual Biological Samples" means any left-over part of Biological Samples remaining after the processing and analyses carried out according to the Study Protocol and/or Sub-Study as well as any Biological Samples initially collected, processed and stored for Follow-On Studies. Residual Biological Samples include but are not limited to: formalin-fixed paraffin embedded (FFPE) tumour tissue, tumour tissue microarrays (TMAs), snap frozen tumour tissue, extracted tumour RNA/DNA as well as blood, plasma and PGx samples (blood and/or DNA).

2.3 Data

"**Data"** means all data collected regarding the patients recruited within the framework of the Studies, in any format whatsoever, whether such data was reported in the Case Report Forms ("**CRFs**"); or, on ancillary data

collections forms; or, whether captured by electronic means, including but not limited to electronic (scanned) images of stained slides already available (i.e. no cutting of new slides is needed).

Compliance with Applicable Laws: all RP Proposals shall comply with applicable laws, rules, regulations, guidance, guidelines and standards relating to data protection (including but not limited to the General Data Protection Regulation EU2016/679), as amended from time to time, with respect to the processing and securing of Data.

Personal data of applicant, co-applicant and institution's employees: the institution and applicant expressly consent to authorize the collection, processing and transfer of institution's and applicant's personal data to countries other than institution's and applicant's own country, even though data protection may not be as developed there. Novartis shall use reasonable efforts to achieve an appropriate level of confidentiality and data protection, when reviewing the RP Proposal.

In this policy Study Data (SD) means Data as per the CTA; and Data means SD and results generated by RPs.

2.4 Custodianship and Ownership

All Residual Biological Samples are stored on behalf of the Studies' Steering Committee ("**SC**"), which is the custodian of the Biological Samples and Residual Biological Samples, at Instituto Europeo di Oncologia (IEO) in Milan for ALTTO and at Vall d'Hebron Institute of Oncology (VHIO) in Barcelona for Neo-ALTTO. Shipping costs of the requested Residual Biological Samples are under the investigator'(s') responsibility.

All SD are owned by BIG and IJB.

Governance:

The SC is the ultimate governing body of the Studies and makes the final decision on the approval of the RP Proposals.

The TRANSALTTO Committee ("**TrAC**") is a group of clinicians and scientists, with demonstrated expertise in translational research, that will be involved in the translational aspects of the ALTTO studies (for both Neo-ALTTO and ALTTO). Endorsed by, and functioning under the governance of the SC, the TrAC is an advisory body for translational projects that are already embedded within the Study Protocols, in addition to being a reviewing body for RP Proposals (refer to TransALTTO Committee Guidelines version 1.1 from 12th of June 2015 for details).
The responsibilities of the TrAC include the following:

- Provide advice (and any necessary recommendations) on translational research projects requiring the use of Residual Biological Samples already embedded in the Study Protocols to the Joint Study Management Team and SC when required
- Review, vote on and recommend RP Proposals requiring the use of Residual Biological Samples and Data for final approval by the SC.

2.5 Requirements for RP Proposals

All RP Proposals, in addition to representing outstanding scientific merit in order to obtain approval, must:

- Specify exactly what types and amount of Data and/or Residual Biological Samples are needed, based upon the proposed analysis and the statistical rationale;
- Be compatible with this policy and contractual commitments developed for the Studies (including but not limited to Intellectual Property Rights (IPR));
- Be self-funded with description of potential funding sources.
- Comply with applicable laws.

If a RP Proposal requires additional ethical-scientific review (as decided by the scientific reviewers), ethical-legal experts will be appointed by the TrAC chairs (for RP Proposals requiring Residual Biological Samples with/without Data) or by the SC chairs (for RP Proposals requiring Data only).

In case researchers are asked to make any changes to their RP Proposal, every effort should be made to implement the changes within 5 working days.

The content of all RP Proposals shall be kept confidential by all reviewers.

2.6 Informed Consent for use of Residual Biological Samples and Data in RPs

Residual Biological Samples and Data must be only used for the purposes defined in the RP, approved in accordance with the present Policy, provided that they are consistent with the study participant's consent obtained for the original study.

All RP Proposals require confirmation from the Novartis Precision Medicine (assoc.) Director (on behalf of the Tykerb global program team) whether the scope of the RP Proposal is covered by the ICFs signed by the patients or not.

When the research use intended is inconsistent with or beyond the scope of the original consent, the RP Proposal will be rejected.

2.7 Types of RP Proposals

There are two different types of RP Proposals:

1) *RP Proposals requiring Residual Biological Samples (with/without Data)*

As a general principle, the SC will propose a given number of calls per year for RP Proposals requiring access to Residual Biological Samples (with/without Data), depending on the Residual Biological Samples availability.

A distinction, in name only, shall be made between internal and external RP Proposals, as follows:

a) Internal RP Proposals: These are proposals made by researchers who have contributed to the Studies in any form or manner, such as investigators and members of any Studies committees (EC, SC, TrAC, Cardiac Advisory Board (CAB)).

b) External RP Proposals: These are proposals made by researchers from the wider scientific community not involved with the Studies.

In addition, RP Proposals which request access to the Alliance Residual Biological Samples will also need to be submitted to the National Cancer Institute ("**NCI**") for additional scientific review and approval. NCI review will be performed on all such RP Proposals which have been already approved by the SC. This process is under the responsibility of the researcher.

The data set used in analyses for all abstracts and publications should be the one derived from the IJB database, prepared by FS and provided to the researcher by IJB. The RP Proposal must also clearly identify the statistician involved in the RP design and performing the analyses.

2) *RP Proposals requiring Data only*

Once an endpoint defined in the protocol has been reached, the corresponding analysis performed, and the data related to the endpoint released through the first public presentation, requests for access to Data (without Residual Biological Samples) may be made at any time, with no deadline for submission set up front.

In exceptional cases (e.g. studies pertaining to study methodology, epidemiology, studies of outstanding scientific merit and study participant benefit, etc.) some controlled access may be given to the Data before the related endpoints have been reached, after approval by the SC. These Data will however not include details on the study treatment received, response, recurrence, or adverse events.

The data set used in analyses for all abstracts and publications should be the one derived from the IJB database, prepared by FS and provided to the researcher by IJB. The RP Proposal must also clearly identify the statistician involved in the RP design and performing the analyses.

2.8 Review and approval of RP Proposals

- All RP Proposals must follow the review and approval process as described in this policy.
- Before being submitted to the SC for approval,
    - A Feasibility review by FS will be made, i.e. an assessment of availability of the clinical data sets and/or samples' derived data and/or samples; FS may seek support from IJB for information on samples/ samples derived data.
    - A limited group of reviewers will perform an in-depth scientific review as follows:

    - For Data only proposals: representatives of the BIG Headquarters and FS will perform a basic scientific review and will decide if the individual RP Proposal could be recommended to the SC for approval or if a more in-depth review is needed with the rationale of this decision (recommendation or review) provided to the SC.

      The SC chair(s) appoint(s) 2 (two) voting members of the SC to evaluate the RP Proposals requiring a more in-depth review.

    - For RP requiring access to Data and Residual Biological Samples,: the TrAC chair appoints 3 (three) TrAC voting members to evaluate the scientific aspects of all RP Proposals per call. A different set of evaluators will be assigned for each call. The scientific review of the 3 TrAC voting members is followed by a consensus teleconference (TC) for the TrAC, during which a final evaluation and a prioritization (in case of redundant or overlapping objectives) of the RP Proposals will be discussed and voted on.
- If similar RPs are submitted (redundant or overlapping objectives and equal scientific merit), the SC can encourage collaboration. In the cases where the SC encourages collaboration, but it is not possible, the decision on the RP Proposal to be approved is made upon vote of the SC.

2.9 Conflict of interest

- If an RP Proposal for accessing data is submitted by BIG HQ or FS, the basic scientific review step is not performed, and an in-depth review will be done by the 2 SC members appointed by the SC chair.
- The SC or TrAC member(s) will be excluded from the evaluation of any RP in which they, or individuals from their institution/organization participate. In case of conflict, they will be replaced by a different SC or TrAC member assigned by the SC chair or the TrAC chair.

2.10 Changes to a RP Proposal

BIG HQ must be informed of any changes that an investigator intends to apply to an approved RP Proposal. Administrative changes that do not affect the scientific aspects of the RP, the number of Residual Biological Samples required or the amount of Data requested, do not need to be re-evaluated by the TrAC and/or SC. If the changes affect the scientific aspects of the RP, the number of Residual Biological Samples required or the amount of Data requested, the RPCC will submit the changes to the SC chairs (Data-only proposals) or TrAC chairs (proposals requiring Residual Biological Samples with/without Data) who will decide whether a new RP Proposal needs to be submitted during the following call, or whether the changes can be sent to the SC for endorsement. The appointed evaluators (i.e. SC or TrAC chairs) will need to have no conflict of interest with the RP Proposal.

2.11 Contractual Commitments

All RPs will require a materials transfer agreement ("**MTA**") /data transfer agreement ("**DTA**") /material use agreement ("**MUA**") to be signed by the applicant, BIG, IJB and Frontier Science (FS), and, in case of an RP requesting material, the facility where the required samples are stored, which will detail the RP information and budget and clauses related to data ownership, intellectual property rights, publication, confidentiality,

possible exploitation issues and budget. This agreement includes a subset of non-negotiable clauses, such as the IPR rules.

BIG shall ensure that:

(a) the terms of the MTA/ DTA/ MUA provide Novartis with all rights granted in the CTA (including any and all amendments thereto) and that the terms of the MTA / DTA / MUA contain those provisions of the CTA (including any amendments thereto) which safeguard Novartis' interests. Such rights and interests include without limitation all rights and interests relating to intellectual property, ownership and confidentiality; and that the MTAs/DTAs/MUAs are consistent with the terms of the CTA;

(b) the items listed below, shall be incorporated *mutatis mutandis* in the MTA / DTA / MUA:

Regardless of when or what type of Data/ Residual Biological Samples are released, the following conditions will apply:

1. The Data/ Residual Biological Samples shall only be used for the purpose for which they have been approved. If the researcher(s) later wish(es) to use the same Data/ Residual Biological Samples for another purpose, another request is required to be submitted. Data/ Residual Biological Samples should be kept secure after transfer to the researcher(s).
2. Transfer of information, Data/ Residual Biological Samples to anyone, not specified in the approved RP and the corresponding MTA/MUA/DTA is prohibited.
3. The Data must be kept confidential by all reviewers (central team, TrAC when applicable and SC).
4. All regulatory and legal requirements for the use and/or processing of Data/ Residual Biological Samples must be met.
5. If a patient withdraws consent and the site submits a sample destruction form to IJB, IJB shall inform the central lab that will ensure that any remaining Residual Biological Samples from that patient are destroyed. IJB shall inform BIG of the request for sample destruction.

2.12 Execution of the RP

All RPs must be performed as per the proposal approved by the SC. Two SC members (for RP requiring access to SD only) or, one TrAC member and one SC member (in the case of an RP requiring access to RP BS) will serve as advisors to the researcher, and will follow the RP up to publication, to ensure that the RP is executed in accordance with the proposal approved by the SC.

Researchers are expected to provide regular updates to the assigned SC/TrAC members (every 6 months after data transfer).

2.13 Left-over Residual Biological Samples

After completion of the RP, any and all left-over Residual Biological Samples shall be returned to the relevant tissue repository that the Residual Biological Sample was taken from under the responsibility and at the expense of the investigator(s). Only with written permission from the SC can left-over Residual Biological Samples be stored in the Investigator's laboratory. Such permission shall detail the future handling and storage of the Residual Biological Samples. Any additional usage of the left-over Residual Biological Samples, beyond the initial RP Proposal, must undergo another review process (including feasibility review) and be approved by the SC.

2.14 Publications / Presentations

The following principles apply for all proposed abstracts, publications or presentations on RP that were approved by the SC:

- Publications are expected to have a draft version circulated for review to the authors within 2 years of data transfer.

- They should not report data from the primary research questions related to the efficacy parameters that have not been publicly presented or published.
- They should not be presented or published prior to the first major publication of the study, unless the SC agrees otherwise.
- The content of the RP presentation/publication should be kept confidential until presentation/publication.
- Researchers must inform BIG HQ/Novartis/SC of planned publication/presentation before submission to a journal/conference, for review as follows:

    - After approval of the RPs (as defined in the Policy for Access to Data and Research Project Biological Samples), for each RP, two SC members (for Data only proposals) or one SC member and one TrAC member, (for RP requesting access to Residual Biological Samples), who have been assigned to serve as link between the RP and SC/TrAC, will review the proposed publication or presentation, on behalf of the SC. They will review and approve the material to be published/presented within ten (10) working days for a publication and five (5) working days for a presentation upon receiving the publication/presentation. Conditional on their contribution to the conduct of the RP and its associated publication or presentation, the designated SC and/or TrAC members might have an authorship position.

    - In addition to the SC/TrAC members assigned to a RP, the authorship for RP publication or presentation is defined by the team performing the RP, as identified in the RP Proposal form, to include and acknowledge those contributing to the RP. SC approval of the authorship as defined by the RP team is not required.

    - Prior to submission of a proposed publication or presentation, Novartis, shall have the right to review and comment on the content of the material to be published or presented. The principal author of the RP publication /presentation will provide the final draft version of the RP presentation/publication for Novartis' review to BIG HQ, with the two SC members (for Data only proposals) or one SC member and one TrAC member, (for RP requesting access to RP BS), in copy; and will wait to receive Novartis' feedback from BIG HQ before proceeding with the submission. Novartis shall have the right to have deleted any confidential information provided by Novartis to a Partner pursuant to the Clinical Trial Agreement or any amendment thereto. This is applicable for Internal Proposals since external researcher will not receive any confidential information. The time frame to complete the review shall not exceed thirty (30) calendar days after receipt by Novartis. However, during this review period, Novartis may request delay of submission for an additional period up to a maximum of ninety (90) calendar days from the original submission to Novartis. This is for the sole purpose of deciding on Patent filing. If such a delay is imposed, Novartis will notify the principal author.

- All publications and presentations must properly acknowledge the study as the source of the SD and Residual Biological Samples used in the RP, and the TrAC (for RPs requesting access to RP Biological Samples), SC, Study Partners, all participating investigators and patients. Acknowledgement of particular individuals may be requested on a case-by-case basis.
- Copies of all final manuscripts/abstracts arising from the RP which are accepted for presentation or publication must be sent to the SC for information.

2.15 Results generated by the approved (under this Policy) RPs

Results mean all data, including raw data, collected, generated or derived from the RP, conducted by a Partner or a Third Party.

To the extent that the investigator of the RP does not have contractual restrictions from a funding party regarding the disclosure of Results, Novartis shall receive a copy of such Results, within sixty (60) days of completion of the RP. Novartis shall retain the Results in confidence and use such Results for its and its Affiliates own internal Research and Development purposes only. Novartis shall not otherwise use or disclose the Results until such Results are published or become part of the public domain, whichever occurs first, except for Novartis to comply with global laws and regulations.

All investigators of the RP Proposals approved under this Policy must agree with making the Results generated by their RP available with study participant ID (preferred option; this is the number allocated to the study participant in the original study) or with sample ID if participant ID was not shared with the researcher initially for potential future use in other RPs (with appropriate acknowledgment of the RP investigator having generated such data). The researcher is responsible to provide the data availability on a patient level (i.e., a list of available data) to the data management center within one month of the publication of the RP.

The investigator of the RP whose data will be used will be asked if he/she is willing to contribute to the new RP. If interested, and conditional on his/her contribution to the conduct of the RP and its associated publication or presentation, authorship may be considered.

Any request for access to and use of data generated as a result of the RP from an investigator different from the one generating the data must be submitted for approval as a new RP.

In the event that the approved RP requests access to results of a former RP, a DTA between the entities of the former RP and the new RP should be signed for the transfer of the results of the former RP, in addition to the DTA/MTA signed for access to the SD and/or RP BS. Unlike the DTA/MTA signed for access to the SD and/or RP BS, the additional DTA between the two RP entities is not coordinated by BIG HQ and should be coordinated by one of the two entities. BIG HQ will send one email to both researchers to inform them accordingly.

The ownership of any Inventions arising from the performance of any Follow-On Study will be determined in accordance with the US laws of inventorship as amended by any relevant contractual arrangements, including those entered into by the inventor(s). BIG and IJB will ensure that the owner of any such Invention, including any Partner, grants the rights to Novartis as indicated below:

1. For all Inventions related to Tykerb®/Tyverb®, including Biomarker Inventions, arising from the performance of any Follow-On Study ("Inventions A"), Novartis is granted a fully-paid, fee-free, royalty-free, exclusive, worldwide license, with the right to sublicense, for any and all purposes, including commercial. Partners are granted a fully paid, non-exclusive, non-sub-licensable license, to use such Inventions A for research and educational purposes only; provided that, neither a pharmaceutical, nor a biotechnology company are supporting such research and the terms of any support do not conflict with those contained herein, without the prior written consent of Novartis.
2. For any Inventions related to Tykerb®/Tyverb® in combination with another agent molecule, or drug, including, without limitation, Herceptin® (hereinafter "Research Agent"), arising from the performance of a Follow-On Study("Inventions B"), Novartis is granted a fully-paid-up, fee-free, royalty-free, co-exclusive worldwide license, with the right to sublicense, for any and all purposes, including commercial and the owner, person or entity having legal rights to the Research Agent are granted an exclusive, non-terminable, ninety (90) day option to a co-exclusive, worldwide license, with the right to sublicense, for any and all purposes, including commercial. In the event the owner, person or entity having legal rights to the Research Agent does not exercise its option within the ninety (90) day period, or fails to reach agreement on the co-exclusive license terms, then the co-exclusive license granted to Novartis hereunder shall revert to a fully-paid-up, fee-free, royalty-free non-exclusive worldwide license, with the right to sublicense, for any and all purposes, including commercial. Partners are granted a fully-paid, non-exclusive, non-sub-licensable license to use such Inventions B for research and educational purposes only; provided that, neither a pharmaceutical, nor a biotechnology company

are supporting such research and the terms of any support do not conflict with those contained herein, without the prior written consent of Novartis.

3. For any Inventions not related to Tykerb®/Tyverb® or the combination of Tykerb®/Tyverb® with a Research Agent, arising from the performance of a Follow-On Study ("Inventions C"), Novartis is granted a fully-paid-up, fee-free, royalty-free, non-exclusive worldwide license, with the right to sublicense, for any and all purposes, including commercial. Partners are granted a fully-paid, non-exclusive, sub-licensable license to use such Inventions C for any and all purposes, including commercial. In addition, Partners shall have the right to grant sub-licenses to any Third Party, to use such Inventions C for any and all purposes, including commercial, provided that the terms of such sub-license does not conflict with the terms contained herein.

4. In the event that any study or Follow-On Study is conducted outside the Protocol using SD and/or Residual Biological Studies but without either (i) approval by the SC or (ii) approval by the TrAC and endorsed by the SC, any invention arising from such study shall be governed by the provisions above, as well as the publication policy and the clauses related to the access to the Results.

3. Procedures from submission of RP Proposals until data/samples transfer

- Researchers must fill in the Research Project Proposal template ("RPP template" – see Appendix 1 and 2 of the Policy) providing all required information and submit the proposal to the FS' Research Project Proposals Coordinator ("RPPC") who will coordinate the review and approval process.
- Timelines for review:
  - For RP Proposals requiring access to Data and Residual Biological Samples, it is estimated that researcher will be informed about the SC decision 60-80 working days after the submission deadline. In case the requested data or RP BS are not available, the researcher will be informed about the rejection within 16-25 WD after the submission deadline.
  - For RP Proposals requiring access to Data only: RP Proposals will be reviewed latest on a quarterly basis
- The RPPC will inform the researcher about the SC decision: "Approve", "Conditionally Approve" or "Reject", including the rationale for the decision in case of rejection, or conditional approval.
- For projects that are "conditionally approved", it is the responsibility of the researcher to ensure that the RP Proposals is adapted according to the SC comments and provided via the RPPC to the SC, within six (6) months, for a final decision. If this period is exceeded the RP Proposal will be rejected.
- Proposals that are "Rejected" may be re-submitted for a full review after suitably addressing the concerns and comments raised by the TrAC or the SC. The process will stop after the second rejection of the RP Proposal by the SC.
- Once an RP is approved, the negotiation and sign-off of an MTA/DTA and preparation of the data sets and biomaterial can start as follows:

  1. *Materials transfer agreement ("**MTA**")*
     - For Non-US samples, BIG HQ and the researcher will liaise with each other to set up a MTA. The MTA will need to be signed by the investigator's institution, BIG, IJB, the sample transferring entity and any other Principal Investigator indicated in the RP Proposal. The MTA will be drafted and signed by all parties within approximately 2 months.
     - For RPs involving US samples, after having received the NCI approval, the researcher will contact Mayo Clinic's biobank directly to set up a MTA/MUA for the US Residual Biological Samples & Data.
     - BIG will ensure that any MTA / MUA that will be established provides Novartis with all rights granted in the CTA (including any and all amendments thereto) and is consistent with the terms of the CTA.

- BIG informs IJB, FS and IEO/VHIO (for ALTTO/NeoALTTO respectively) when a MTA is fully executed within 3 WD. For sake of clarity, no data or Residual Biological Material will be transferred to investigators conducting RPs without a previous confirmation from BIG that the MTA is fully executed.
- Dataset(s) will be prepared by FS after they receive the confirmation from BIG that the MTA is fully executed. FS will aim to initiate contact with the researcher within 3 months of the DTA signature. The investigator/research statistician shall discuss and agree the required variables with the FS statisticians. Once the SD are ready, FS will prepare and forward to IJB the requested SD within 4 calendar weeks . IJB will transfer the SD to the investigators within 4 calendar weeks from the moment the datasets are received from FS .
- In case the RP researcher has questions regarding the samples received (s)he will contact the respective sample transferring entity directly. In case the RP researcher has questions regarding the data received, (s)he will contact directly FS regarding the questions related to Data and/or the researcher of the initial RP regarding questions related to the results generated by the initial RP.

2. *Data transfer agreement ("**DTA**")*
   - The researcher will liaise with BIG HQ to set up a DTA. The DTA will need to be signed by the investigator's institution, BIG, IJB and any other Principal Investigator of the RP Proposal. The DTA will be drafted and signed by all parties within approximately 2 months.
   - BIG will ensure that any DTA that will be established provides Novartis with all rights granted in the CTA (including any and all amendments thereto) and is consistent with the terms of the CTA.
   - BIG informs IJB and FS when a DTA is fully executed within 3 WD. For sake of clarity, no data will be transferred to investigators conducting RPs without a previous confirmation from BIG that the DTA is fully executed.
   - Dataset(s) will be prepared by FS after they receive the confirmation from BIG that the DTA is fully executed. FS will aim to initiate contact with the researcher within 3 months of the DTA signature. The investigator/research statistician shall discuss and agree the required variables with the FS statisticians. Once the SD are ready, FS will prepare and forward to IJB the requested SD within 4 calendar weeks. IJB will transfer the SD to the investigator within 4 calendar weeks from the moment the data sets are received from FS.
   - In case the RP research has questions regarding the data received, (s)he will contact directly FS regarding the questions related to Data and/or the researcher of the initial RP regarding questions related the results generated by the initial RP.

4. Appendices

1. Research Project Proposal template - completion instructions
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