NRG ONCOLOGY

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Guidance for Use of Data Developed with Collaborator Support

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OVERVIEW

As a National Institutes of Health (NIH) National Cancer Institute (NCI) funded organization, NRG Oncology is required to share anonymized clinical data from its published studies according to its NCI-approved Data Sharing Policy. The procedures for requesting published data are outlined in the Data Sharing Policy. Additionally, NRG Oncology is required to place data from primary publications of phase 3 trials published after January 1, 2015, as well as selected non-primary publications of phase 3 trials published after April 1, 2018 in the NCI NCTN/NCORP Data Archive with imaging data available from The Cancer Imaging Archive (TCIA). Access to data in the Data Archive is at the discretion of the NCI. Access to unpublished secondary or exploratory clinical trial data from clinical trials that have published their primary endpoints is available through the Ancillary Project request process.

NRG Oncology and its member foundations, the GOG, NSABP and RTOG Foundations (Foundations) value their collaborations with their academic and for-profit industry partners (Collaborators) who may fund clinical trial analysis activities, such as biospecimen and imaging analyses, which are not supported by grant funding. NRG Oncology and/or its Foundations will enter into funding and confidentiality agreements with these Collaborators to support this work. The following Guidance will help govern the analyses of data generated from these collaborations.

NRG Oncology Guidance for the Use of Data Developed with Collaborator Support, "Collaboration Data"

1. "Data" is defined as all data and information including clinical data and metadata, generated by NRG Oncology via its participating facilities and research sites, as a result of conducting an NRG Oncology study.
2. Data resulting from the conduct of NRG Oncology's clinical research and provided by a participating facility to NRG Oncology or to a participating research site or designated contracted entity at the direction of NRG Oncology, constitutes property entrusted to the care and management of NRG Oncology to be used for the benefit of the public, and NRG Oncology is the owner and guardian of such Data. Unless otherwise addressed, all worldwide right, title and interest in the intellectual property rights with respect to such Data shall be owned and retained by NRG Oncology or the individual Foundation on behalf of NRG Oncology.
3. NRG Oncology reserves the right to use all Data for commercial and non-commercial academic research activities.
4. "Collaboration Data" is defined as Data that was developed with Collaborator support that has not been published. It is considered confidential and can only be shared with entities other than the funding Collaborator with the approval of the Collaborator and pursuant to provisions codified in a collaborator agreement.
5. NRG Oncology and/or its Foundations will not perform studies that make use of Collaboration Data funded by two or more different Collaborators without the express written consent of the Collaborators.
6. Once study results using the Collaboration Data have been published, the published information is no longer considered confidential and are available for provision to outside parties subject to NRG Oncology's Data Sharing Policy. As the policy describes, there may be additional constraints or requirements on data provided and its use.
7. The data that is available under NRG Oncology's Data Sharing Policy or through the Ancillary Project request process may be limited to the data derived from the raw data that remains

proprietary to a Collaborator or a service provider. For example, if imaging, genomic or laboratory data is used to categorize patients into subsets (such as low, intermediate or high risk), the data set will identify an individual patient's risk subset, but not necessarily include the raw data supporting that patient's inclusion in the subset if it was generated by a Collaborator or service provider. Ancillary Projects necessarily involve NRG Oncology oversight, as results represent research output of NRG Oncology.

8. This Guidance is to be read contemporaneously with any applicable Federal guidelines, including but not limited to the NCI NCTN Program Guidelines and the NCI Cancer Therapy Evaluation Program (CTEP) Intellectual Property Option for Collaborators. For the avoidance of doubt, if any provision in this guidance shall conflict with applicable Federal guidelines, the Federal guidelines shall prevail.