MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Guidance Document Submission
Division of Dockets Management (HFA-305)
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Attn: Julie Burger Chronis, JD

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The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center) and many other institutions have been committed to efforts to ensure the appropriate and timely communication of aggregate research results to study participants and the general public.[1] Furthermore, over the last few years, the Health Research Authority in the United Kingdom and the European Medicines Agency have been finalizing policies and a guidance to ensure such communication are understandable and accessible to a general audience; they anticipate requiring posting of these result summaries, written in plain language with appropriate translations for the countries where the studies were conducted, as soon as the latter part of 2018. That said, we are well aware that participant and patient communities in geographies beyond the EU also desire to learn of the results of clinical trials in which they have participated.

To date, the US Food and Drug Administration (FDA) has not communicated endorsement of the development and provision of plain language summaries to research participants or the general public, although we believe that such affirmation would be helpful to sponsors and sponsor-investigators. We believe that FDA would be supportive of voluntary efforts to develop and provide plain language summaries, if certain conditions were met.

In collaboration with TransCelerate Biopharma, Inc., the MRCT Center adapted the principles outlined by the MRCT guidance and toolkit to draft a document for consideration by FDA. This document is meant to provide stakeholder input toward a potential FDA guidance on the development and dissemination of plain language summaries to participants and the general public. Further, as an indication of support and consensus around this input and the value of a future guidance, a number of additional signatories including patient advocacy groups, professional associations, and others have endorsed this input.

We therefore respectfully submit our input under the authorizing statute, Good Guidance Practices at 21 CFR 10.115(f)(2)-(3) which invites the stakeholder community to submit guidance topics and draft guidances.

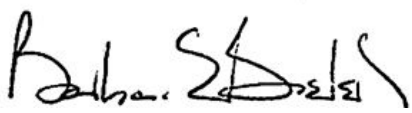
Please consider the attached document that we provide with the intent to help the agency and in our

[1] The MRCT Center has developed a Guidance Document and Toolkit for the return of aggregate results. http://mrctcenter.org/projects/return-of-results-to-participants/

shared desire to serve the needs of the public and study participants, We are happy to discuss further and to offer assistance if it would be helpful to the agency in any way.

We look forward to hearing from you.

We remain,
Very truly yours,



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On behalf of:

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Allergy & Asthma Network, Tonya A. Winders, President and CEO
American Federation for Aging Research
American Epilepsy Society
American Heart Association
American Society of Clinical Oncology
Arthritis Foundation
Association of Clinical Research Professionals
Autism Speaks
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Bladder Cancer Advocacy Network
Bonnie J. Addario Lung Cancer Foundation
BreastCancerTrials.org
CancerCare
Cancer Support Community
Center for Information and Study on Clinical Research Participation (CISCRP)
Chesapeake IRB
European Cancer Patient Coalition
FORCE: Facing Our Risk of Cancer Empowered
Genentech, a member of the Roche Group
GlaxoSmithKline
Global Liver Institute, Donna R. Cryer, JD President & CEO
Melanoma Research Alliance (MRA)
Merck & Co., Inc.
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