POLICY

Clinical Trial Data Sharing Policy

1. PURPOSE

This policy establishes the responsibilities of Celgene employees and contractors with respect to clinical trial data sharing and study registration and results initiatives.

Celgene is committed to providing information about its clinical trials to researchers and patients with the goal of furthering science and enhancing the lives of patients worldwide.

While honoring this commitment, Celgene will ensure patient privacy and the protection of confidential and commercially sensitive information, as well as publication rights, in accordance with applicable laws and regulations.

2. SCOPE

This policy applies to all employees and contractors of Celgene involved in clinical trial data sharing and study registration and results activities.

This policy (1) describes data sharing activities relating to studies supporting indications approved in both the United States and European Union on or after January 1, 2014, and (2) provides for lay summaries and other study registration and results initiatives.

Celgene will continue with ongoing data disclosure activities in accordance with legal and regulatory requirements promulgated by the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA) and other competent authorities as described herein.

This policy addresses:

- public access to clinical study information;
- public access to clinical trial results;
- data sharing with researchers; and
- sharing results with patients who participate in clinical trials.

Cooperative Group clinical studies, which may be part of regulatory submissions, and Investigator Initiated Trials, are not within the scope of this policy because they are not Celgene sponsored studies.

3. DEFINITIONS

3.1. Anonymisation

The result of the de-identification process to remove or disguise personal information in study documents or a study database, such that study data for an individual cannot be identified or linked back to the individual.

3.2. Celgene-sponsored study

A clinical study in which Celgene is responsible for its initiation, management, and/or financing.

3.3. Clinical Trial Results

Information to inform healthcare providers and the public about the trial outcomes as well as adverse events.

3.4. Publication

The term "publication" includes a broad range of projects which could be congress-related (e.g. abstract, poster, oral presentation) and/or manuscripts (e.g. article, case study, review article, meta-analysis, sub-group analysis, letter to the editor, etc…)

3.5. Redaction

The editing of a document to remove, mask, or delete privileged or confidential information.

4. ROLES AND RESPONSIBILITIES

4.1. Scientific Review Board (SRB)

A group of individuals selected by the Celgene Clinical Trial Data Sharing Steering Committee composed of external experts to provide an unbiased review of research proposals submitted by researchers to ensure that the proposals are robust, scientifically sound with a valid and clearly defined hypothesis and include both an analysis and publication plan. A Celgene employee will assist with meeting facilitation but will not be a voting member.

4.2. Celgene Clinical Trial Data Sharing Steering Committee

The responsibilities of the Steering Committee are:

- to monitor and provide direction for the data sharing activities and commitments set forth in this policy;
- to select the SRB members; and
- to review data sharing requests for appropriateness of review by the SRB for studies supporting indications that have not been approved on or after January 1, 2014 in both the United States and European Union.

The Steering Committee will be composed of representatives from Celgene Senior Leadership that includes members from at least the following groups: Clinical Research, Medical Affairs, Regulatory Affairs, Legal and Corporate Affairs.

5. STANDARDS

5.1. Data Sharing

The SRB will consider providing qualified researchers with redacted and anonymised data from studies supporting indications approved in both the United States and European Union on or after January 1, 2014. Data Sharing requests outside of this scope will also be considered depending on availability of the data and assessment of the scientific validity of the request.

Considering the need to allow sufficient time for publication of results, clinical trial data will be made available within a reasonable time following regulatory approval of submissions in both the United States and the European Union.

5.1.1. Data Types for Disclosure

All data must be anonymised to protect the privacy of the patients who participated in Celgene-sponsored studies, in accordance with applicable laws and regulations and in compliance with the International Conference on Harmonization and Good Clinical Practice (ICH/GCP).

Consent forms for studies initiated on or after January 1, 2014 must inform patients of the potential for anonymised disclosure of their data.

Information that will be considered for disclosure includes:

- patient-level clinical data*;
- study-level clinical data*;
- Clinical Study Reports (CSR);
- Annotated Case Report Forms (CRF) or documents explaining data structure;
- Statistical Analysis Plans (SAP); and
- Protocols.

*Raw and derived data sets

5.1.2. Submitting a Request

All requests must include a description of the research proposal and be submitted to Celgene by completing an online request form at www.CelgeneClinicalDataSharing.com.

5.1.3. Review Process

Internal Celgene personnel will initially review each request to ensure alignment with the scope of the policy and completeness of the request as well as check current or expected availability of the data sets. Following the initial review, a request will be submitted to the SRB for final review and approval. The SRB will review each proposal to determine if it is robust, scientifically sound, and has a valid and clearly defined hypothesis including an analysis and publication plan. They will also evaluate the qualifications and experience of the research team to conduct the proposed research. The names of the SRB members will be disclosed at www.CelgeneClinicalDataSharing.com.

5.1.4. Approval of Requests

Following approval by the SRB and the receipt of a fully executed Data Sharing Agreement, the researcher will be provided access to redacted documents and/or anonymised, analyzable data sets necessary to carry out the requested research. Access to the documents and data will generally be provided for a period of up to two years.

5.1.5. Final Results

Consistent with the Data Use Agreement, the Celgene Clinical Trial Data Sharing Steering Committee will review the results to ensure the protection of Celgene confidential information and intellectual property rights.

5.1.6. Data Sharing Requests

Celgene will ensure that all data requests (including research proposals, outcome of requests, status of ongoing/completed research projects, and summary results of completed projects) are posted on a public website.

5.2. Clinical Trial Registration

5.2.1. Registration of Clinical Trials

Celgene will continue to (1) register all Celgene-sponsored studies in individuals with disease prior to obtaining the first consent, on the public database

www.ClinicalTrials.gov regardless of where the study is being conducted, and (2) register all Celgene-sponsored studies conducted in Europe in the relevant official system. All Celgene-sponsored studies also will be registered on national registries as required by local regulations.

5.2.2. Clinical Trial Results

Clinical trial results will be disclosed in a variety of ways:

Results Posting on Clinical Trial Registry Public Websites

Celgene posts on public websites the trial progress, results, and associated documents relating to Celgene-sponsored studies as required by national and regional regulations.

Clinical Study Report Synopses

Celgene posts on public websites the redacted Clinical Study Report synopses for Celgene sponsored studies in individuals with disease supporting indications approved in both the United States and European Union on or after January 1, 2014. In addition, if contractual agreements allow, Celgene will post clinical study synopses for Cooperative Group and Investigator Initiated trials used to support an approval in the United States and European Union on or after January 1, 2014.

Lay Summaries to Study Participants

Celgene will provide lay summaries from all Celgene-sponsored studies in individuals with disease that were initiated on or after January 1, 2014 to inform and educate them about their clinical trial participation.

Publications

Celgene is committed to disclosing clinical trial information and providing the results in the form of publication.

Celgene will ensure Celgene-sponsored studies are considered for publication in scientific literature irrespective of the results. This commitment also includes results relating to investigational medicines whose development programs have been discontinued.

6. REFERENCES

- PhRMA and EFPIA: Principles for Responsible Clinical Trial Data Sharing 18July2013
- 2007 FDA Amendments Act
- Directive 2001/20/EC of the European Parliament
- Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014
- POL-CORP-ADM06 – Data Protection and Privacy Policy