

2020 Work Plan

Cell Therapy Working Group (CTWG)

Date: 29 October 2019

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1. KEY MILESTONES AND DELIVERABLES

1.1. Current status of key milestones and deliverables

Past completion date	Objective	Key Milestone or Deliverable
October 2018	Develop a reflection paper	Principles to address the nature and duration of follow-up for clinical trial subjects
October 2019	Gather regulatory frameworks from participating regulators.	In collaboration with the gene therapy working group, frameworks from 10 regulatory agencies were collected.

1.2. Future anticipated key milestones

Expected future completion date	Objective	Key Milestone or Deliverable
August 2020	Communicate the outcome of the framework project to the public.	Working with the GTWG, publish a manuscript on the frameworks project.
May 2020	Identify topics for a reflection paper	Reflection Paper

2. TIMELINE FOR SPECIFIC TASKS

Beginning date	End date	Task / Activity	Details
November 2019	November 2019	Teleconference	Topics: drafting committee for the framework project, discussion of new topics for reflection paper, participation in the ISCT Annual Meeting in Paris, May 2020.
February 2020	March 2020	Collaborate with Gene Therapy Working Group on manuscript.	Initiate work on a draft manuscript
March 2020	June 2020	Drafting of manuscript	Drafting within the core drafting group.
June 2020	August 2020	Circulate manuscript among regulators	Commenting and editing of draft manuscript.
October 2020	December 2020	Clearance of manuscript by regulatory authorities.	Circulate final draft for permission to publish from regulatory authorities.
Expected January 2021		Acceptance of the manuscript by IPRP MC	Manuscript to be submitted to MC and then journal for publication.

3. SUMMARY OF ANY CURRENT ISSUE

The CTWG is seeking advice on adding new member countries to the working group. It is important to note that for this working group adding new countries/new individuals to the working group fulfils the mandate to provide an open forum to 1) Maintain knowledge of regulatory activities in participating regions; 2) Identify topics for regulatory convergence; 3) Collaboration and information sharing with other international (ICH) and regional bodies (APEC, PANDRH, etc) and to collaborate in terms of training of international regulators.

4. NECESSITY FOR FACE-TO-FACE MEETING

To further the preparation of a manuscript on the framework project and to initiate a new topic, the CTWG along with the drafting committee members from the Gene Therapy Working Group may meet in-person on the margins of the International Society for Cellular Therapy (ISCT) Annual Meeting in Paris, May 27 – 30, 2020. This will be discussed at the November 2019 teleconference.