

Work Plan

Cell Therapy Working Group (CTWG)

Date: 10 October 2021

Secretariat: Judith Arcidiacono, FDA, United States

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.
October 2020	Regulatory Framework Project (RFP)	Tabulated results
September 2021	RFP	Published Regulatory Frameworks on IPRP website

1.2. Future anticipated key milestones

Expected future completion date	Objective	Key Milestone or Deliverable
May 2022	Compilation of Guidance, Guideline and Reflection Paper	Work with the GTWG to publish tables on RFs
May 2022	Publish journal manuscript introducing availability of FRP outcomes	Publication of manuscript in journal
June 2022	Raw Materials Project	Draft Reflection Paper



November 2022	Compile list of marketed products for participating regions	Publish list of marketed products on IPRP website
	participating regions	

2. TIMELINE FOR SPECIFIC TASKS

Beginning date	End date	Task / Activity	Details
October 2021	May 2022	Publish list of Guidance/Guidelines/Reflection Papers (GGRP)	 a. Create table for guidelines/guidance b. Request update to information originally collected in 2019 c. Submit to MC for review d. Publish list on IPRP website
October 2021	February 2022	Finalization of RFP tables	Regulators review RFP tables for accuracy and completeness
February 2022		WG teleconference #24	
April 2022	March 2022	Publish List of Marketed Products	a. Compile list b. Review list c. Submit list to MC d. Publish list on IPRP website
May 2021	November 2022	Raw Materials Reflection Paper	a. Create survey b. Draft Outline c. Establish drafting committee d. Prepare draft e. Review draft and collect comments f. Submit draft to MC g. Publish reflection paper to IPRP website
November 2022	May 2023	Update Frameworks, GGRP, and Marketed products	a. Request updates from participants b. Compile updates c. Submit updates to MC



	d. Publish updated information on IPRP website