

# 2021 Work Plan Cell Therapy Working Group (CTWG)

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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.	
October 2020	Regulatory Framework Project (RFP)	Tabulated results	

## 1.2. Future anticipated key milestones

Expected future completion date	Objective	Key Milestone or Deliverable
June 2021	Public availability of RFP results	Work with the GTWG to publish tables on RFs
June 2021	Prepare manuscript for notice of availability of RFP	Publication of manuscript



# 2. TIMELINE FOR SPECIFIC TASKS

Beginning date	End date	Task / Activity	Details
October 2020	December 2020	Revise RFP tables	<ul> <li>a. Add weblinks to tables</li> <li>b. Create table for guidelines/guidance</li> <li>c. Send revised tables to WG for review</li> <li>d. Provide framework template to new members (Israel, Chile, Malaysia, and Indonesia)</li> </ul>
January 2021	February 2021	Finalization of RFP tables	Regulators review RFP tables for accuracy and completeness
February 2021		WG teleconference #21	Discuss RFP and new project on raw materials
May 2021	June 2021	Complete first stage of regulatory RF project	Post finalized RFP tables and publish notice of availability
May 2021	June 2021	WG teleconference #22	Initiate raw materials project Discuss next steps for RFP
October 2021	November 2021	WG teleconference #23	To be determined