

## 2021 Draft Work Plan

### Gene Therapy Working Group (GTWG)

Date: 22 October 2020

**Secretariat:** Judith Arcidiacono, FDA, United States

#### Key Milestones and Deliverables

##### 1.1. Current status of key milestones and deliverables

<b>Past completion date</b>	<b>Objective</b>	<b>Key Milestone or Deliverable</b>
June 2019	ICH Guideline	ICH accepted Japan's proposal to further develop the GTWG Reflection Paper on Biodistribution of Gene Therapy Vectors
October 2019	Regulatory Framework Project (RFP)	Gather regulatory frameworks from participating regulators. In collaboration with the Cell Therapy Working Group (CTWG) frameworks from 10 regulatory agencies were collected.
March 2020	Teleconference	Discussed launch of Long-Term Follow-up Reflection Paper
October 2020	RFP	Results tabulated and output discussed in CTWG

##### 1.2. Future anticipated key milestones

<b>Expected future completion date</b>	<b>Objective</b>	<b>Key Milestone or Deliverable</b>
June 2021	Public availability of RFP results	Work with CTWG to publish RFP tables on IPRP website
June 2021	Prepare manuscript for Notice of Availability (NoA) for RFP	Work with CTWG to draft a notice of availability
July/August 2021	Publish NoA	Review/approval of NoA by MC.

On hold pending the availability of experts	Initiate project on convergence of approaches for Long Term Follow-up (LTFU) for patients receiving gene therapy products.	US FDA and EMA to present outline to WG after reviewing each agency's guidelines and guidances.
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## 2. TIMELINE FOR SPECIFIC TASKS

Beginning date	End date	Task / Activity	Details
October 2020	December 2020	Revise RFP tables as suggested by CTWG	<ul style="list-style-type: none"> <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>
November 2020		Teleconference # 27	
January 2021	February 2021	Finalization of RFP tables	Regulators review RFP tables for accuracy and completeness
March/April 2021		Teleconference #28	
September/October 2021		Teleconference #29	