

Work Plan

Nanomedicines Working Group

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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
2016	<i>Information Sharing & Mapping - Liposomes</i>	<i>IPRP NWG Liposome Survey results published on the NWG landing page of the IPRP website</i>
January 2018	<i>Information Sharing & Mapping</i>	<i>JRC Technical report: Mapping Nanomedicine Terminology in the Regulatory Landscape published on the NWG landing page of the IPRP website</i>
Apr 2020	<i>Information Sharing & Mapping - Liposomes</i>	<i>Liposome survey published on the NWG landing page of IPRP website</i>
Jun 2021	<i>Information Sharing & Mapping - Liposomes</i>	<i>Liposome survey analysis completed and updated to the NWG</i>
Sep-Dec 2021	<i>Information Sharing & Mapping</i>	<i>Zoom Nano proposal announced; inaugural presentation delivered Dec 2021</i>
Nov 2021 -Nov 2022	<i>Identification of NWG agency expertise and needs</i>	<i>Chat One-on-One with 10 regulatory agencies Chair and Co-chair conduct a 30-min phone call with individual agency representatives</i>
May 2022	<i>Information Sharing & Mapping</i>	<i>Members presented at virtual regulatory session at CLINAM May 2022 meeting</i>
Oct 2022	<i>Information Sharing & Mapping</i>	<i>Members presented at in-person Global Summit Regulatory Science (GSRS) Oct 2022 meeting</i>
Jan - Nov 2022	<i>Information Sharing & Mapping</i>	<i>Six Zoom Nano presentations delivered</i>

1.2. Future anticipated key milestones

Expected future completion date	Objective	Key Milestone or Deliverable
June 2023	<i>Information Sharing & Mapping - Liposomes</i>	<i>Publish Liposome Survey on a peer-reviewed journal</i>
On hold due to COVID work. To be discussed whether this task will be continued or not	<i>Development of proposal for enabling/enhancing collaborative regulatory research between regulatory agencies</i>	<ul style="list-style-type: none"> - <i>Finalizing questionnaires and databases to catalogue interested research laboratories/researchers and research needs by May 2021</i> - <i>Distribution of research needs and laboratories interested/available for collaborative studies – August 2021</i>
2023 - quarterly	<i>Information sharing/training</i>	<i>Zoom Nano - Regulatory Considerations for lipid nanoparticle platform technologies used to deliver mRNA/DNA vaccines, gene therapies and siRNA</i>
2023	<i>Organize 2023 face-to-face meeting</i>	<i>Plan and organize face-to-face meeting, discuss regulatory issues and research of lipid nanoparticles and provide training on liposome standards</i>

2. TIMELINE FOR SPECIFIC TASKS

Beginning date	End date	Task / Activity	Details
<i>Dec 2022</i>	<i>December 2023</i>	<i>Teleconferences</i>	<i>Quarterly</i>
<i>Dec 2022</i>	<i>December 2023</i>	<i>Support liposome standards development and dissemination</i>	<ol style="list-style-type: none"> 1. <i>A number of liposome standards were developed by ISO and ASTM. IPRP NWG will help disseminate these standards and provide trainings to member agencies.</i> 2. <i>IPRP NWG will also help prioritize and review future standards for liposome products and other nanomedicines.</i>
<i>Dec 2022</i>	<i>December 2023</i>	<i>Zoom Nano - Information sharing and mapping, regulatory updates, training</i>	<i>Theme 2: lipid nanoparticle platform technologies used to deliver mRNA/DNA vaccines, gene therapies and siRNA</i>

			<p><i>Identified as a topic of interest to WG members as a result of the rapid development of mRNA vaccines for Covid-19, and also during the course of Liposome survey project</i></p> <p><i>Initially planned as information exchange on review experiences and potential harmonization.</i></p>
<i>Dec 2022</i>	<i>December 2023</i>	<i>Nanomedicine guideline library</i>	<i>Archive guidelines published by NWG member agencies on sharepoint site; review English translations of regional guidelines</i>
<i>Sep 2019</i>	<i>June 2023</i>	<i>Liposome Survey Report</i>	<p><i>Publish analysis of 2021 Liposome Survey on IPRP website and notify stakeholders</i></p> <p><i>Identify and plan follow-on activities (e.g. write Reflection Paper)</i></p>
<i>Sep 2023</i>	<i>Dec 2023</i>	<i>Develop 2024 Work Plan</i>	