

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</i>	<i>IPRP NMWG Liposome Survey results published on the NMWG 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 NMWG landing page of the IPRP website</i>
Apr 2020	<i>Information Sharing & Mapping</i>	<i>Liposome survey published on the NMWG landing page of IPRP website</i>
Jun 2021	<i>Information Sharing & Mapping</i>	<i>Liposome survey analysis completed and updated to the NMWG</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>

Jan – Nov 2023	<i>Information Sharing & Mapping</i>	<i>Three Zoom Nano presentations delivered</i>
Jan – Mar 2023	<i>Support liposome standards development and dissemination</i>	<i>Three most recent liposome standards shared among the group</i>
Jan – Nov 2023	<i>Information Sharing & Mapping</i>	<i>Archived guidelines published by NWG member agencies and other regional updates on SharePoint site</i>
Oct 2023	<i>Information Sharing & Mapping</i>	<i>Held face-to-face meeting, discussed regulatory issues and research of lipid nanoparticles and product-specific guidances</i>
Jan - Nov 2023	<i>Identification of NWG agency expertise and needs</i>	<i>Chat One-on-One with 3 regulatory agencies Chair and Co-chair conducted a 30-min phone call with individual agency representatives</i>
Jan – Nov 2024	<i>Information Sharing & Mapping</i>	<i>Continued previous work efforts and established 2 new sub working groups: 1) Lipid Nanoparticle working group- <u>reached consensus on active pharmaceutical ingredient (API) vs excipient determination in lipid nanoparticles</u>; 2) Doxorubicin HCl Liposome Product-specific guidance working group</i>

1.2. Future anticipated key milestones

Expected future completion date	Objective	Key Milestone or Deliverable
2025 - quarterly	<i>Information sharing/training</i>	<i>Hold quarterly teleconference</i>
2025 - quarterly	<i>Information sharing/training</i>	<i>Zoom Nano Webinar</i>
2025- Ad hoc	<i>Information sharing/training/consensus building</i>	<i>Sub working group meetings</i>
Jan – Oct 2025	<i>Evaluate and plan 2025 face-to-face meeting</i>	<i>Evaluate the feasibility of holding a face-to-face meeting If feasible, plan and organize face-to-face meeting</i>

2. TIMELINE FOR SPECIFIC TASKS

Beginning date	End date	Task / Activity	Details
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<i>Dec 2024</i>	<i>Dec 2025</i>	<i>Teleconferences</i>	<i>Hold quarterly meeting to discuss emerging topics related to nanomedicine development and regulation</i>
<i>Dec 2024</i>	<i>Dec 2025</i>	<i>Zoom Nano Information sharing and mapping, regulatory updates, training</i>	<i>Hold at least 3 webinars. Exchange review practice of CTD for nanomedicines</i>
<i>Dec 2024</i>	<i>Dec 2025</i>	<i>Doxorubicin HCl liposome Injection Product-specific guidance (PSG) Subgroup</i>	<ul style="list-style-type: none"> • Continue collecting survey information/updates from different agencies • Draft a document summarizing the scientific considerations for the PSG. • Facilitate further discussion on the varied approaches from member agencies to deepen our collective understanding
<i>Dec 2024</i>	<i>Dec 2025</i>	<i>Lipid Nanoparticle (LNP) Subgroup</i>	<ul style="list-style-type: none"> • Continue updating and summarize survey results • Liaise with other expert groups to discuss guidance documents • Provide trainings on lipid nanoparticle characterization/testing, e.g., particle size analysis
<i>Sep 2025</i>	<i>Dec 2025</i>	<i>Develop 2026 Work Plan</i>	