

Work Plan

Nanomedicines

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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
<i>January 2016</i>	<i>Identification of Regulatory Needs for nanomedicines</i>	<i>JRC Publication: Identification of regulatory needs for nanomedicines (1st EU-NCL survey with the NMWG of the IPRP; published on the NMWG landing page of the IPRP website</i>
<i>January 2016</i>	<i>Information Sharing & Mapping</i>	<i>Poster: JRC Technical report: Mapping Nanomedicine Terminology in the Regulatory Landscape published on the NMWG landing page of the IPRP website</i>
<i>2016</i>	<i>Information Sharing & Mapping - Liposomes</i>	<i>IPRP NMWG Liposome Survey results published on the NMWG landing page of the IPRP website</i>
<i>January 2018</i>	<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>

1.2. Future anticipated key milestones

Expected future completion date	Objective	Key Milestone or Deliverable
<i>June 2021</i>	<i>Information Sharing & Mapping - Liposomes</i>	<i>Updated Liposome Survey to be published</i>

<i>Ongoing</i>	<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>
<i>2021 - bimonthly</i>	<i>Information sharing/training</i>	<i>Presentations of case studies or training to working group members through WebEx seminars</i>
<i>01/2020</i>	<i>Organize 2021/2022 face-to-face meeting</i>	<i>Plan and organize face-to-face meeting at CLINAM 2021/22 (pandemic permitting)</i>

2. TIMELINE FOR SPECIFIC TASKS

Beginning date	End date	Task / Activity	Details
<i>January 2021</i>	<i>December 2021</i>	<i>WebEx meetings - Information sharing and mapping, regulatory updates, training</i>	<ul style="list-style-type: none"> • <i>Non-confidential updates on nanomedicine portfolios (general numbers of applications, types of products, etc) at bimonthly TCs</i> • <i>Compilation and sharing of regulatory documents for nanomedicines and follow-on nanomedicines through publication to the sharepoint site, including Documentary test method standards and reference material that enable product development</i> • <i>Sharing/attendance of learning and training opportunities offered by IPRP members - Virtual training presentations and case studies delivered by group</i>

			<p><i>members during bimonthly TCs</i></p> <ul style="list-style-type: none"> • <i>Potential extension of training opportunities to nano-enable medical devices</i>
<i>January 2019</i>	<i>ongoing</i>	<i>Liposome Survey Report</i>	<ul style="list-style-type: none"> • <i>Publish analysis of 2020 Liposome Survey on IPRP website and notify stakeholders</i> • <i>Identify and plan follow-on activities (e.g. write Reflection Paper)</i>
<i>January 2020</i>	<i>ongoing</i>	<i>Development of proposal for enabling/enhancing collaborative regulatory research between regulatory agencies</i>	<ul style="list-style-type: none"> - <i>IPRP management committee approval for proposal– Nov/Dec 2019</i> - <i>Finalizing questionnaires and databases to catalogue interested research laboratories/researchers and research needs by June 2021 – was due for discussion at face-to-face meeting</i> - <i>Distribution of research needs and laboratories interested/available for collaborative studies – August 2021</i>
<i>January 2021</i>	<i>December 2021</i>	<i>Develop Project - Regulatory Approaches and Potential for Harmonisation of Platform Technologies, including lipid nanoparticle platform technologies used to deliver mRNA/DNA vaccines, gene therapies and siRNA</i>	<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>