7 November 2024
EMA/515876/2024

Revised list of enabling tools

Start of public consultation	7 November 2024
End of consultation (deadline for comments)	30 November 2024

Comments should be provided using this EUSurvey form. For any technical issues, please contact EUSurvey Support.

1. Background

As part of EMA's horizon scanning and foresight activities, applicants to EMA procedures are asked to highlight the enabling tools and technologies[1] applied in their development programs. This information is requested either when registering a Research Product Identifier (RPI) in IRIS (an EMA platform for submitting applications electronically), or when applying to an Innovation Task Force (ITF) meeting. The revised list of enabling tools is open for public consultation until 30 November 2024.

[1] *Enabling tools are defined as novel technologies that have the potential to enable innovation in the context of medicines development. They can refer to a novel therapeutic approach, a novel category of medicinal product or a technology or methodology integrated in the pre-clinical, clinical or CMC dossier of a medicine.*

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2. Revised list of enabling tools (draft)

Domain	Enabling tools
Non-clinical / Clinical	**Alternative to antimicrobials**, e.g. phage therapy
	Gene therapy, including gene editing technology
	Somatic cell therapy and tissue-engineering, including stem cell-based medicinal product
	Synthetic biology
	Artificial intelligence applied to pre-clinical data and/or clinical data
Manufacturing / Quality	**3D printing and 3D bioprinting**
	Advanced manufacturing, e.g. AI applied to quality and manufacturing, continuous manufacturing, pharmaceutical process model, digitalization, new manufacturing facility design and manufacturing platforms
	Decentralized manufacturing, e.g. bedside, point of care and mobile/portable manufacturing
	Smart/advanced material, e.g. stimuli-responsive
	Novel excipient
	New medicine delivery system
	Nanotechnology
	Advanced analytical technologies, e.g. next generation sequencing, multi-attribute method
Methodology	**New Approach Methodology (NAM) and 3Rs principles**, e.g. *in silico* model, *in vitro* model, digital twins, organs-on-chips
	Novel biomarker, novel endpoint
	Data sources, e.g. Real World Data, big data, registries, pharmacogenomics, biobank data
	Complex clinical trial, e.g. platform/umbrella, basket trial, Bayesian design, adaptive design
	Decentralized clinical trial elements, e.g. home delivery of the investigational medicinal product, trial-related procedures at home, data management and monitoring in a decentralised clinical trial setting
	Extrapolation strategy
	Artificial intelligence applied to regulatory compliance

Domain	Enabling tools
	Digital technologies, e.g. e-health, digital endpoints, blockchain, trials integrated with electronic healthcare system
Complex / Borderline product	**Medical device**, including software as medical device
	Procedure involving germ cells
	Other complex/borderline product, e.g. blood-derived product
Other enabling technology	Click or tap here to enter text.