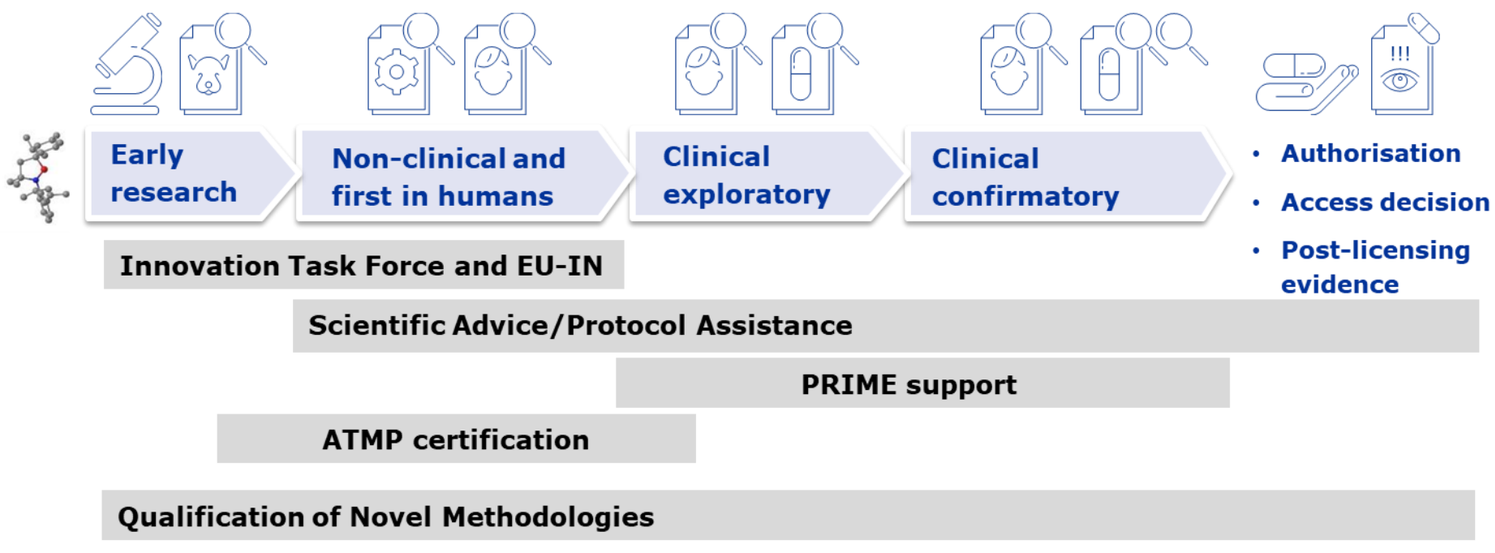
EMA Services for Medicinal Products and Novel Technologies						
	ITF[1] Briefing Meeting	**ATMP Classification**	**ATMP Certification**	**Scientific Advice**	**PRIME Scheme**	**SME briefing meeting**
Stage of development	Recommended at early stage (after proof of concept) for innovative technologies, substances and methods related to medicines development. However, ITF is available at any stage for those that are particularly innovative or disruptive.	Early (no expectation of non-clinical or clinical development)	Some data have been generated on pharmaceutical quality and, optionally, on non-clinical aspects.	At any stage of development but early advice with subsequent follow-up is recommended.	Clinical exploratory: with compelling non-clinical data and tolerability data from initial clinical trials Exceptionally, SMEs can access PRIME based on proof of concept data and first in human trial	SME briefing meetings are available at any stage of a product development.
Goal	To receive informal regulatory and scientific input	To determine whether a medicine being developed meets the scientific criteria of an ATMP, and thus whether it is classified as a gene, cell or tissue engineered medicinal product.	To give SMEs developing ATMPs an assessment of the data they have generated and check that they are on the right track for successful development.	Ensure key aspects of the development plan is in line with regulatory expectations.	To support the expedited development of medicines for an unmet medical need by an early dialogue with developers of promising medicines, to optimise development plans and speed up the evaluation so these medicines can reach the patients earlier.	Platform to discuss the regulatory strategy of a medicinal product development and navigate the range of procedures and incentives available at EMA level.
Area	Broad area, any products, technologies and methodologies	Gene, cell and tissue engineered products	Gene and cell therapies, and tissue engineered products	1. Development of any medicinal products. 2. For novel methodologies for drug development not yet integrated in the drug development and clinical management paradigm.	Medicines addressing unmet medical needs.	All product types and therapeutic indications. Human and Veterinary medicinal products
Advice	Multidisciplinary informal dialogue on scientific, legal and regulatory issues	Whether a medicine under development is an ATMP. Optional: classification	How existing data correspond to requirements for marketing authorisation	Prospective in nature - focusing on pre-identified questions from the applicant regarding their development strategy rather than pre-evaluation of data to support a MAA and giving advice on the most appropriate way to generate robust evidence on a medicine's benefits and risks.	Early and proactive advice through Scientific Advice to optimise the generation of robust data on a medicine's benefits and risks and enable accelerated assessment of medicines applications	Multidisciplinary assistance by EMA team. Topics : applying for scientific advice/protocol assistance (quality, nonclinical, clinical); regulatory and procedural topics for marketing authorisation application submission; gaining access to SME incentives; orphan drug designation and paediatric requirements; PRIME eligibility; pre/post-licensing evidence generation.
Outcome	Informal. A report with the regulatory experts' recommendations and considerations.	Informal. Conclusions if ATMP applies and, if asked, which type of ATMP.	Formal. Certificate together with an evaluation report and CAT opinion.	Formal. Clarifying the scientific requirements for MA, e.g. Manufacturing, non-clinical and clinical trials, risk-management plans, ways to develop generics, etc. Qualification of innovative methodologies for medicine development and, if appropriate, letter of support from CHMP.	Formal. Written confirmation of PRIME eligibility and potential for accelerated assessment; early CHMP; kick off meeting with multidisciplinary expertise from EU network; enhanced scientific advice at key development milestones/decision points; EMA dedicated contact point	Informal; meeting minutes for company's records with EMA comments.
Possible follow up	Recommendation for scientific advice	Experts recommendation for scientific advice	Experts recommendation for scientific advice, follow-up certification possible as development proceeds.		Experts recommendation and fee incentives for Academia and SMEs for scientific advice.	Follow-up SME briefing meeting possible, recommendation for other EMA procedures such as scientific advice or PRIME.
Eligibility SMEs	YES	YES	YES (only for SMEs)	YES	YES	YES (only for SMEs)
Eligibility Academia	YES	YES	No	YES	YES	NO
Cost	Free to SMEs Free to Academia	Free to SMEs Free to Academia	• Fee depending on whether non-clinical data to be evaluated or not	• Fee depending on status: • 90 % fee reduction for SMEs, free for orphan designated products • Fee charged to Academia[2] • 65 % fee reduction on ATMP for Academia • Free for advice on orphan or paediatric medicine	Free eligibility	Open to SMEs Free of charge

[1] **ITF** Innovation Task Force; **ATMP** Advanced Therapy Medicinal Product; **CHMP** Committee for Medicinal Products for Human Use; **MA** Marketing Authorization & **MAA** Marketing Authorization Application; **PRIME** Priority Medicine**.** [2]For fees please see https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/explanatory-note-general-fees-payable-european-medicines-agency-1-april-2021_en.pdf

STAGES OF DEVELOPMENT



FOR MORE INFORMATION

See training slides and recording of the EMA webinar available for 2 years on EU Learn:" Webinar on EMA Innovation Support Services". Also see some of the webinary publicly available here: https://www.youtube.com/user/emainfo/videos

URLs from more information on the EMA web site and EMA Contacts

Recommended entry points

- SME office SME@ema.europa.eu
- Academia entry point Academia@ema.europa.eu
- EMA's frequently updated user guide: it helps navigating the regulatory requirements and incentives available throughout a medicine's product lifecycle, providing an overview of support for research and development activities, improving understanding of what is needed to obtain marketing authorisation: https://www.ema.europa.eu/en/human-regulatory/overview/supporting-smes#-sme-user-guide-section

ITF (Innovation Task Force) Briefing Meeting

- To know more https://www.ema.europa.eu/en/human-regulatory/research-development/innovation-medicines#itf-briefing-meetings-section
- To apply **https://www.ema.europa.eu/en/human-regulatory/research-development/innovation-medicines#applying-for-a-briefing-meeting-section**

ITF Scientific Recommendation on Advanced Therapy Medicinal Product (ATMP)

- To know more and apply https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/advanced-therapies/advanced-therapy-classification

Scientific Advice

- To know more https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-advice-protocol-assistance
- To apply https://www.ema.europa.eu/en/human-regulatory/research-development/innovation-medicines#applying-for-a-briefing-meeting-section
- To apply for novel methodologies for drug development: contact scientificadvice@ema.europa.eu and read https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/qualification-novel-methodologies-drug-development-guidance-applicants_en.pdf
- Fee information for academia https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/explanatory-note-general-fees-payable-european-medicines-agency-1-april-2021_en.pdf

PRIME Scheme

- To know more https://www.ema.europa.eu/en/human-regulatory/research-development/prime-priority-medicines

- To apply **https://www.ema.europa.eu/en/human-regulatory/research-development/prime-priority-medicines#how-to-apply-section**

Medical Devices

- EMA is responsible for evaluating the quality, safety and efficacy of marketing authorisation applications assessed through the centralised procedure, including the safety and performance of the medical device in relation to its use with the medicinal product. SMEs and Academia working on medical device can still apply to ITF Briefing Meeting.
- To know more **https://www.ema.europa.eu/en/human-regulatory/overview/medical-devices**