EMA

Tools available to medicine's developers from the academic sector

The European Medicines Agency (EMA) provides regulatory and scientific support to help academics develop medicines.

General guidance for medicines' developers

EMA's interactive tool describes the journey of a medicine authorised via the Agency, from initial research to patient access in the EU, and how EMA works.

EMA's guide for micro, small and medium-sized enterprises provides details about the regulatory processes involved in a marketing authorisation and is aimed at developers which are unfamiliar with the regulatory framework for pharmaceuticals.

Academia fee waiver

Early interaction with EMA is crucial when it comes to developing promising treatments that can benefit patients with rare diseases.

To enhance R&D in this area, EMA is waiving fees for academics when they apply for protocol assistance, a special type of scientific advice for orphan medicines.

Academia entry point

Academia@ema.europa.eu

The entry point addresses the needs of medicines' developers from the academic sector and aims to facilitate communication and help them navigate the regulatory framework for pharmaceuticals.

Qualification of novel methodologies

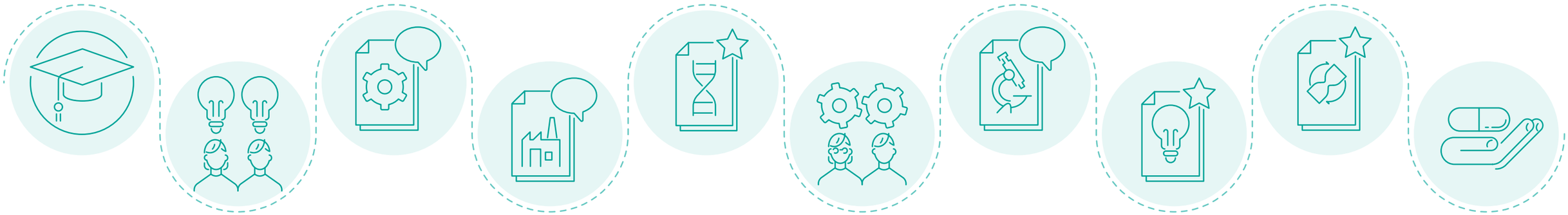
Academic sponsors obtain scientific advice on the regulatory acceptability of novel innovative methods or tools (e.g. novel biomarkers or imaging methods).

Orphan designation

Academic sponsors can apply for orphan designation and benefit from incentives such as protocol assistance, fee and regulatory incentives at time of marketing authorisation.

Scientific advice & Protocol assistance for orphans

EMA can provide scientific advice on quality, non-clinical and clinical development to generate robust evidence for regulatory submissions. Protocol assistance is a special form of scientific advice available for developers of designated orphan medicines to discuss compliance criteria such as demonstration of 'significant benefit' or 'clinical superiority'.



Innovation Task Force (ITF)

ITF provides a forum for early dialogue with medicines' developers to horizon scan scientific, legal and regulatory topics in innovative therapies developments and technologies.

SME (micro, small and medium-sized enterprises) office

The SME office provides administrative and procedural assistance to legally established companies including academic spin offs. SMEs can benefit from briefing meetings to discuss their regulatory strategy, and fee incentives for EMA procedures.

EU Health Technology Assessment (HTA)

EMA's scientific advice offers the possibility of joint advice with EU HTA bodies, enabling to receive advice on evidence-generation for marketing authorisation and health technology assessment decision making (cost-effectiveness assessment of medicines for healthcare systems).

Advanced therapy medicinal products (ATMPs) classification

Academic sponsors consult EMA to determine whether a product meets the definition of an advanced therapy medicinal product (ATMP) and its subcategories (gene therapy, cell therapy, tissue-engineered product).

PRIority MEdicines (PRIME)

PRIME is a dedicated scheme to provide enhanced regulatory support for the development of medicines that target unmet medical needs and have shown promising initial results. Developers receive early confirmation of whether a medicine is eligible to accelerated assessment. Academia and SMEs benefit from early entry into the scheme and additional fee incentives.