Supporting medicine developers in generating quality data packages in early access approaches (PRIME and breakthrough therapies): workshop report published

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EMA and the [US Food and Drug Administration (FDA)](https://www.fda.gov/home) have published today a  [report](https://www.ema.europa.eu/documents/report/report-workshop-stakeholders-support-quality-development-early-access-approaches-ie-prime_en.pdf)  on their [joint workshop with stakeholders](https://www.ema.europa.eu/en/events/stakeholder-workshop-support-quality-development-early-access-approaches-such-prime-breakthrough)held on 26 November 2018. The aim of this workshop was to discuss scientific and regulatory approaches to address quality and manufacturing challenges encountered during the development of medicines under early access programmes, such as the [PRIority MEdicines scheme (PRIME)](https://www.ema.europa.eu/en/human-regulatory/research-development/prime-priority-medicines" \t "_self) in the European Union and the [Breakthrough Therapy designation](https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/breakthrough-therapy) in the United States. The report contains recommendations from participants on next steps and areas to be further explored by EMA and the FDA.

“With PRIME, we have established a platform that supports the development of promising medicines to help patients with unmet medical needs to benefit from these as early as possible,” said EMA's Head of Human Medicines Research and Development Support Division, Enrica Alteri. “Some challenges, for instance to complete quality and manufacturing development and data requirements are universal to early access programs. We have therefore teamed up with our partners at the FDA to organise this workshop and discuss together with pharmaceutical companies possible scientific and regulatory approaches that facilitate the preparation of robust quality data packages. This is the basis which enables timely access to medicines for patients and gives the necessary assurance that patient safety, [efficacy](https://www.ema.europa.eu/en/glossary/efficacy) and product quality are not compromised. We will continue to cooperate with our FDA colleagues to further facilitate the successful development and authorisation of priority medicines.”

The workshop was attended by 56 regulators from the EU [national competent authorities](https://www.ema.europa.eu/en/glossary/national-competent-authority), EMA, the FDA and the [Japanese Pharmaceuticals and Medical Devices Agency (PMDA)](https://www.pmda.go.jp/english/), and 64 industry representatives. It was broadcast live on the EMA website and was followed online by over 2,400 individuals. The presentations and videos are available on the [meeting page](https://www.ema.europa.eu/en/events/stakeholder-workshop-support-quality-development-early-access-approaches-such-prime-breakthrough).

Since the launch of PRIME in March 2016, EMA has received and assessed a total of 246 requests for eligibility. Of these, 55 have been accepted onto the scheme. Through PRIME, the Agency offers early and proactive support to medicine developers to optimise the generation of robust data on a medicine's benefits and risks and enable [accelerated assessment](https://www.ema.europa.eu/en/glossary/accelerated-assessment) of medicines applications.