



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

2 October 2015  
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Management Board meeting of 2 October 2015

## Implementation of EMA policy on publication of clinical data – Status report

Following adoption by the Management Board of the EMA policy on the publication of clinical data at the Board's October 2014 meeting, work has been undertaken to prepare for the implementation of the EMA policy.

Since this is a completely new EMA activity several new arrangements had to be put in place in the most cost-efficient way. This relates to new end-to-end business processes for the different workstreams, the development of external guidance (on the submission of clinical reports for publication, on the identification and redaction of CCI in clinical reports for publication, on the anonymisation of clinical reports for publication). In addition, new IT systems have to be put in place.

The EMA has throughout the preparation for implementation phase continued its interaction with all stakeholders, although a more targeted stakeholder consultation approach has been applied taking into account the complexity of the project and the available timeframe before starting the publication of the clinical reports.

The attached slide deck [EMA/614336/2015] provides further information on the current status of implementation.

