



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Workshop on update of TB Guideline

AIMS AND OBJECTIVES OF THE WORKSHOP

Presented by Mair Powell 25th November 2016
Rapporteur for the Guideline





Rationale for revision of EMA/CHMP/EWP/14377/2008

- The current document was prepared during 2008-10
- It was adopted and came into operation in 2010
- Several new issues came to light during the reviews of bedaquiline and delamanid and as a result of CHMP scientific advice procedures since that time
- Change in focus of new drug/new regimen development, requiring a re-write of the clinical trial design sections



Objectives and aims of the workshop

- The draft revised guidance is currently in public consultation
- Feedback is also elicited via this workshop, especially on:
 - The relevance of the guidance to ongoing programmes
 - The feasibility of the recommendations made
 - Any important omissions that should be addressed
 - The clarity of the guidance



Objectives and aims of the workshop

- The workshop has been organised by topic to reflect the major sections of the draft revised guidance
- In each session it is important to consider what is actually being done, what the guideline suggests should be done and discuss areas needing further revision
- There remain several areas on which a global consensus has not been reached and a degree of flexibility must be maintained, reflecting current scientific knowledge



Objectives and aims of the workshop

- Time has been allotted to discussion during each session
- The aim is to discuss the data and views put forward, as well as the current draft text and any changes that the IDWP might need to consider before finalisation
- Attendees are also encouraged to provide written feedback during the formal consultation process
- A final version is to be adopted by CHMP during 2017



We appreciate that some of you
gave up your holidays

This year, the National
Thanksgiving Turkey that the
president pardons will be chosen
in Iowa and will live at **Gobblers
Rest** at Virginia Tech.
(assuming he is pardoned)



Thank you for your attention

Further information

[Insert relevant information sources or contact details as applicable.]

European Medicines Agency

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom

Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555

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