Break-out session 1

Harmonization in the EU Clinical Trials Framework

Presented by Claire Bahans on 11 Sep 2024

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Clarification on MS requirements

More guidance and updated guidance to ensure harmonized interpretations

Interpretation of CTR and Q&A

Parallel substantial modifications

Management of complex clinical trials

Negative opinion / approval with conditions

Patient facing documents in part II

Notification, NSM, Interim analyses, results : what do MS need ? What should be provided ?

Precision on track 1 survey

Common list of submission fees country by country