02 May 2018
EMA/44715/2018

Agenda for

Workshop on draft reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development

3-4 May 2018

Meeting room 3-A
European Medicines Agency, London, United Kingdom

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Objectives

To discuss comments received during the public consultation phase and aspects related to methodological approaches and practical challenges for comparisons at quality level.

To gain better understanding of challenges and opportunities of statistical methods used at quality level in order to facilitate further progress in this field.

Programme details

Thursday, 3 May 2018

Order of presentations subject to change

08:30 **Registration**

09:00 **Welcome and introduction**

Thomas Lang, BSWP, AGES (AT) & **Ina-Christine Rondak**, EMA *75'*

10:15 **Coffee break**

10:30 **Session A: Problem statements and challenges**

Chair: **Ina-Christine Rondak**, EMA

One size doesn't fit all: Why it should be three different guidances
Bruno Boulanger, EFSPI, Arlenda *20'*

Medicines for Europe's view on the application of statistical methodology for comparability
Martin Schiestl, Medicines for Europe, Sandoz *20'*

Statistical tests, Bayesian analysis, or heuristic rules for demonstration of analytical biosimilarity?
Richard Burdick, AAPS, Elion Labs *20'*

Challenging issues in biosimilar regulatory submission in the United States
Shein-Chung Chow, FDA (USA) *20'*

Discussion introduced by Chair *30'*

12:30 **Lunch break**

13:30 **Session B: Case studies with focus on pre-post manufacturing changes**

Chair: **Martijn van der Plas**, BWP, CBG-MEB (NL)

Considerations on biological APIs extracted from material of human and animal origin
René van Herpen, APIC, Aspen Oss BV *20'*

Comparability study performed to support a process change for a marketed biological product
Jochen Felix Kepert, EBE, Roche *20'*

Pre- and Post-Manufacturing Change for a Biological Product
Christophe Agut, EBE, Sanofi & **Vivien Le Bras**, EBE, Merck *20'*

Comparability study to support commercial process change via stability study

Bianca Teodorescu, EBE, UCB *20'*

Discussion introduced by Chair *30'*

15:30 Coffee break

15:45 Session C: Case studies with focus on Biosimilars

Chair: **Niklas Ekman**, BMWP/BWP, Fimea (FI)

Case studies on statistical tools used for comparability assessment

HyungKi Park, Medicines for Europe, Samsung Bioepis *20'*

Practical considerations in the statistical evaluation of biosimilarity — a laboratory perspective

Henriette Kuehne, AAPS, Coherus BioSciences *20'*

Analytical similarity

José G. Ramírez, EBE, Amgen *20'*

Comparison of Two Groups of Stability Data

Franz Innerbichler, EBE, Novartis *20'*

Discussion introduced by Chair *30'*

18:00 End of day 1 (for external participants)

18:30 Session D: For regulators only

Learnings from day 1

Workshop organisation committee and session Chairs *45'*

19:15 End of day 1 (for all)

08:30 **Welcome and introduction**

08:40 **Session E: Operating characteristics of currently/frequently used similarity criteria**

Chair: **Andreas Brandt**, BSWP, BfArM (DE)

Introduction
Andreas Brandt, BSWP, BfArM (DE) *15'*

Operating characteristics of frequently used similarity rules
Florian Klinglmueller, BSWP, AGES (AT) *20'*

Performance characteristics of quality range methods and equivalence testing in the comparative assessment of quality attributes
Thomas Stangler, Medicines for Europe, Sandoz *25'*

Analytical Similarity Assessment
Shein-Chung Chow, FDA (USA) *20'*

Discussion introduced by Chair *30'*

10:30 **Coffee break**

10:45 **Session F: New Strategies and alternative methodological approaches**

Chair: **Florian Klinglmueller**, BSWP, AGES (AT)

EMA Case Study: Design of Experiments
Robert Shaw, VE, AstraZeneca *20'*

Statistical methodology for biosimilars, comparison of process changes and comparison of dissolution profiles. A perspective from EFSPI
Mike Denham, EFSPI, GlaxoSmithKline *20'*

The value of Bayesian statistics for assessing comparability
Timothy Mutsvari, EFSPI, Arlenda *20'*

Establishing, Assessing, and Comparing Quality Attributes from a Small Sample of Development Batches through Full-scale Production
Kimberly Vukovinsky, ISPE, Pfizer *20'*

Discussion introduced by Chair *30'*

12:40 **Closing remarks**

Thomas Lang, BSWP, AGES (AT) *20'*

13:00	**End of workshop (for external participants)**	
14:00	**Session G: For regulators only**	
	Learnings from day 2	
	Workshop organisation committee and session Chairs	*120'*
16:00	**End of workshop (for all)**	

The workshop organisation committee consists of:
Andreas Brandt, BSWP, BfArM (DE)
Niklas Ekman, BMWP/BWP, Fimea (FI)
Thomas Lang, BSWP, AGES (AT)
Jobst Limberg, QWP, BfArM (DE)
Kit Roes, BSWP, CBG-MEB (NL)
Ina-Christine Rondak, EMA
Martijn van der Plas, BWP, CBG-MEB (NL)

Practical information

Venue

The European Medicines Agency can be reached:

- **By Underground**
  The nearest stop for Churchill Place is Canary Wharf station on the Jubilee Line. From East exit (NB. This is the closest exit to 30 Churchill Place): exit the station and turn left into Upper Bank Street, turn right at Canada Square and continue straight into Churchill Place.

- **By Docklands Light Railway (DLR)**
  The Agency is a short walk from Canary Wharf station on the DLR. Services run from Bank, Tower Gateway, Lewisham, Stratford, King George V and Beckton. Exit into The South Colonnade, turn left towards Canada Square continuing straight into Churchill Place.

- **By car**

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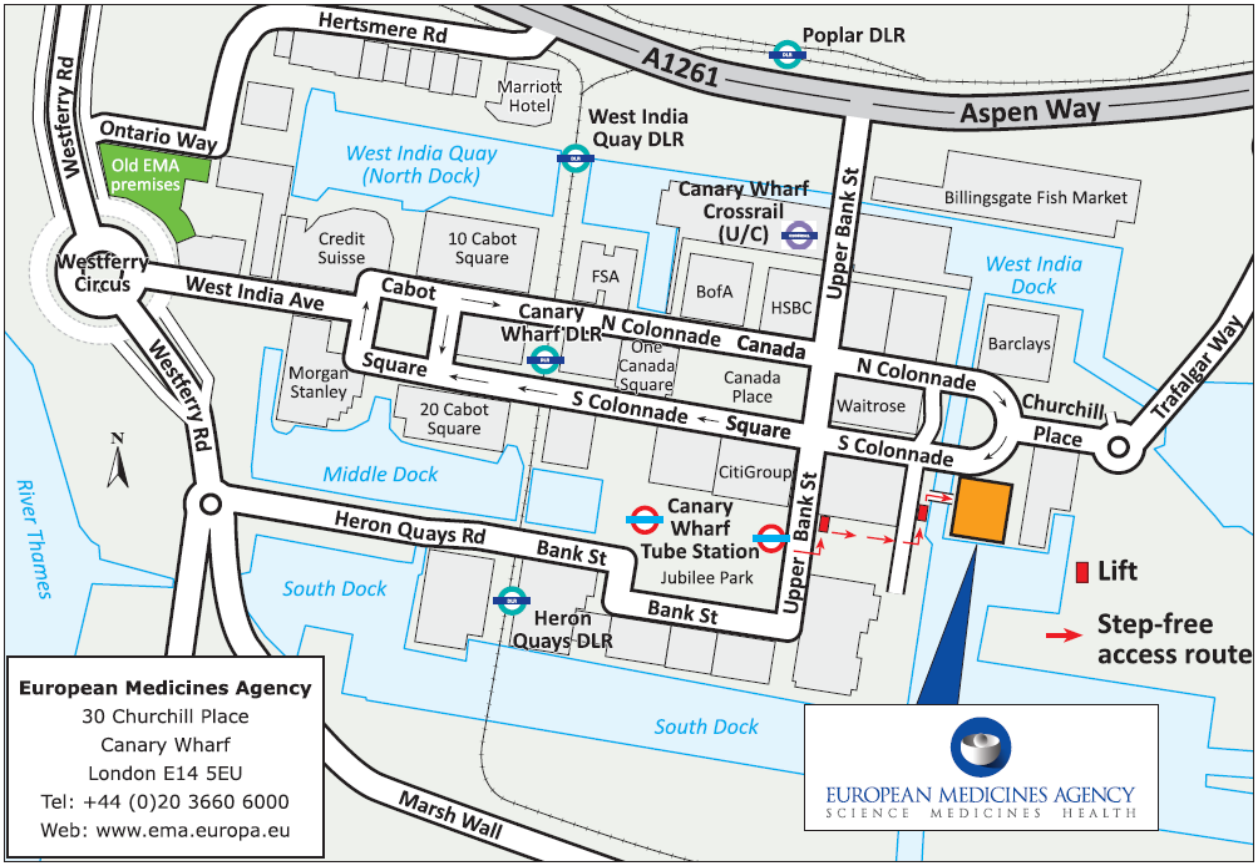
  http://www.canarywharf.com/aboutus/The-Estate/Travel-/Roads--Parking/

Map



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Physical disability

Let us know if you would like any specific help or information that would make your stay more comfortable. We will be very happy to help.

Registration

We strongly advise you to arrive up to 30 minutes before the start of the workshop, to allow you time for registration and settling down.

Meeting room

Upon arrival each day, please find your allocated seat in the meeting room. Speakers will be able to navigate through their presentation slides from their seats with a pointer, mouse or keyboard.

Presentations

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Conference venue and secretariat

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For any questions prior to the workshop in relation to the content and participation, please write to RP-stats-QA@ema.europa.eu.