EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 September 2017
EMA/CHMP/SWP/522061/2017
Human Medicines Research & Development Support Division

First EMA workshop on non-animal approaches in support of medicinal product development – challenges and opportunities for use of micro-physiological systems

Programme

5 October 2017
European Medicines Agency, London, United Kingdom

Meeting room 3A

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
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Send a question via our website www.ema.europa.eu/contact

Objectives of the workshop

The European Medicines Agency is organising a **workshop on organs-on-chip** or micro-physiological systems which is a rapidly progressing and promising field applying the 3Rs principles (replacement, reduction and refinement) in animal experimental testing as detailed in Directive 2010/63/EU.

This workshop is targeted at the non-clinical development of medicinal products and aims at:

- mapping the current state-of-science in this field
- developing a common understanding of the benefits and limits of these methods
- identification of gaps in non-clinical safety testing and stimulating research with these methods in order to address these gaps and finally stimulating use in regulatory testing
- being a forum to encourage the dialogue between developers, users and regulators
- facilitating the regulatory acceptance of innovative non-animal methods for a defined context of use for the approval of safe medicines while promoting the 3Rs principles

Programme overview

Sessions

Session 1: The pharmaceutical industry view

Session 2: Academic & researchers perspective

Session 3: What do regulators want?

Breakout sessions

Round table discussion

Organising Committee:

Sonja Beken – Belgian Federal Agency for Medicines and Health Products (AFMPS)

Jan Willem van der Laan - Dutch Medicines Evaluation Board (MEB), Chair of the Safety Working Party

Christine Mummery – University of Leiden, the Netherlands

Uwe Marx – Technical University of Berlin, Germany

Jean-Marc Vidal, Human Medicines Research and Development Support

Milton Bonelli, Human Medicines Research and Development Support

EMA Support:

Nadja Kriste, Human Medicines Research and Development Support

Programme details

08:30–09:00 Coffee and Registration

The workshop will be held in room 3A. Badges must be collected at the reception on the ground floor.

Chairs **Sonja Beken**

Jan Willem van der Laan

09:00-09:20 Welcome, Health and Safety and organisational matters

Milton Bonelli

09:20-09:35 Opening lecture: Setting the scene / objectives

Sonja Beken

09:35-10:35 Session 1: State of the art: the pharmaceutical industry view

09:35-09:55 Models / methods under development: needs and challenges

Organs on a chip & microphysiological systems in drug development: the need, the vision – and challenges to overcome **(Adrian Roth, Roche)**

09:55-10:15 Place of the models in the R&D strategy

Potential uses of 'organ-on-a-chip' in drug discovery and drug evaluation **(Lorna Ewart, AstraZeneca)**

10:15-10:25 Reliability and limits of the models

MEA assays using human iPSC-derived cardiomyocytes; challenges and opportunities **(Tessa de Korte, Ncardia)**

10:25-10:35 Questions

10:35-11:00 Coffee Break

11:00-12:45 Session 2: State of the art: the academic & research view

11:00-11:20 Challenges for the development of MPS

MPS – development status, first industrial adoption and current challenges **(Uwe Marx, Berlin-DE)**

11:20-11:40 Applications: example of physiological systems

Populating human-on-chip models with induced pluripotent stem cell-derived tissues **(Christine Mummery, Leiden -NL)**

11:40-12:10 In vitro – In vivo extrapolation

In Vitro In Vivo Extrapolation: Why it is not as easy as you may think? **(Amin Rostami, Manchester-UK)**

12:10-12:30 **European partnership for organ-on-chip development**

Organ-on-chip networking in Europe: joining forces for the future **(Janny van den Eijnden-van Raaij)**

12:30-12:45 **Questions**

12:45-13:45 **Lunch break**

13:45-14:25 **Session 3: State of the art: What do regulators want?**

13:45-14:05 **US FDA point of view (Suzanne Fitzpatrick, FDA -** Teleconference**)**

14:05-14:25 **The EMA / SWP point of view**

Detection of Toxicity to Reproduction for Human Pharmaceuticals: Paving the Way for Alternative Assays in the 3rd Revision of ICH S5 **(Günter Waxenecker, SWP)**

14:25-14:30 **Introduction to Breakout sessions (Sonja Beken)**

14:30-15:40 **Breakout sessions**

1. Criteria for regulatory acceptance of Humans on Chip (HOC). Experience with in vivo/in vitro endpoints comparison. Which context of use?
2. How can the regulatory science advance in short and mid-term through the application of HOC. Road map to move forward towards regulatory application of HOC for the most advanced /promising systems.

Proposed moderators (SWP)*: Susanne Brendler-Schwaab (BfArM), Leon van Aerts (MEB), David Jones (MHRA), Günter Waxenecker (AGES), Maria Kovacova (SUKL)*

15:40-16:00 **Coffee Break**

16:00-16:45 **Round table discussion (Sonja Beken, Jan-Willem van der Laan, Suzanne Fitzpatrick, Susanne Brendler-Schwaab, Christine Mummery, Uwe Marx, Industry, European Commission, EMA)**

1. Reports from breakout sessions with identification of action points
2. Information flows: how can we ensure that information feeds method developers <-> regulators <-> pharma <-> method developers to ensure development and qualification of those models that will fill a gap and not put effort in needless exercises.
3. General discussion

16:45-17:00 **Conclusive statements and next steps (Sonja Beken / Jan Willem van der Laan)**

Travel and Accommodation

Participants must possess valid travel documents and, where relevant, a visa for entry into the United Kingdom. Should you require an official letter of invitation, please contact SWP-H@ema.europa.eu.

Recording and Photography

The Agency records or broadcasts a number of its meetings, including some virtual meetings. This is part of the Agency's commitment to the principle of transparency as enshrined in the Treaty on the European Union. The conference will be recorded. By attending these events you consent to any photographing, recording, broadcast and publication of presentations on the EMA website.

WiFi access

WiFi is available throughout the EMA. Login details can be found on the back of your EMA access pass.

Restaurant facilities

Restaurant, deli bar and coffee bar are available (located on 4th floor) - please note you will need to have either £10.00 or €10.00 minimum cash in order to purchase a pre-paid canteen card

There are also many cafes and restaurants in the Canary Wharf area. More information can be found in the Canary Wharf area guide (restaurants, shops, etc.):

www.allinlondon.co.uk/regions/canary-wharf

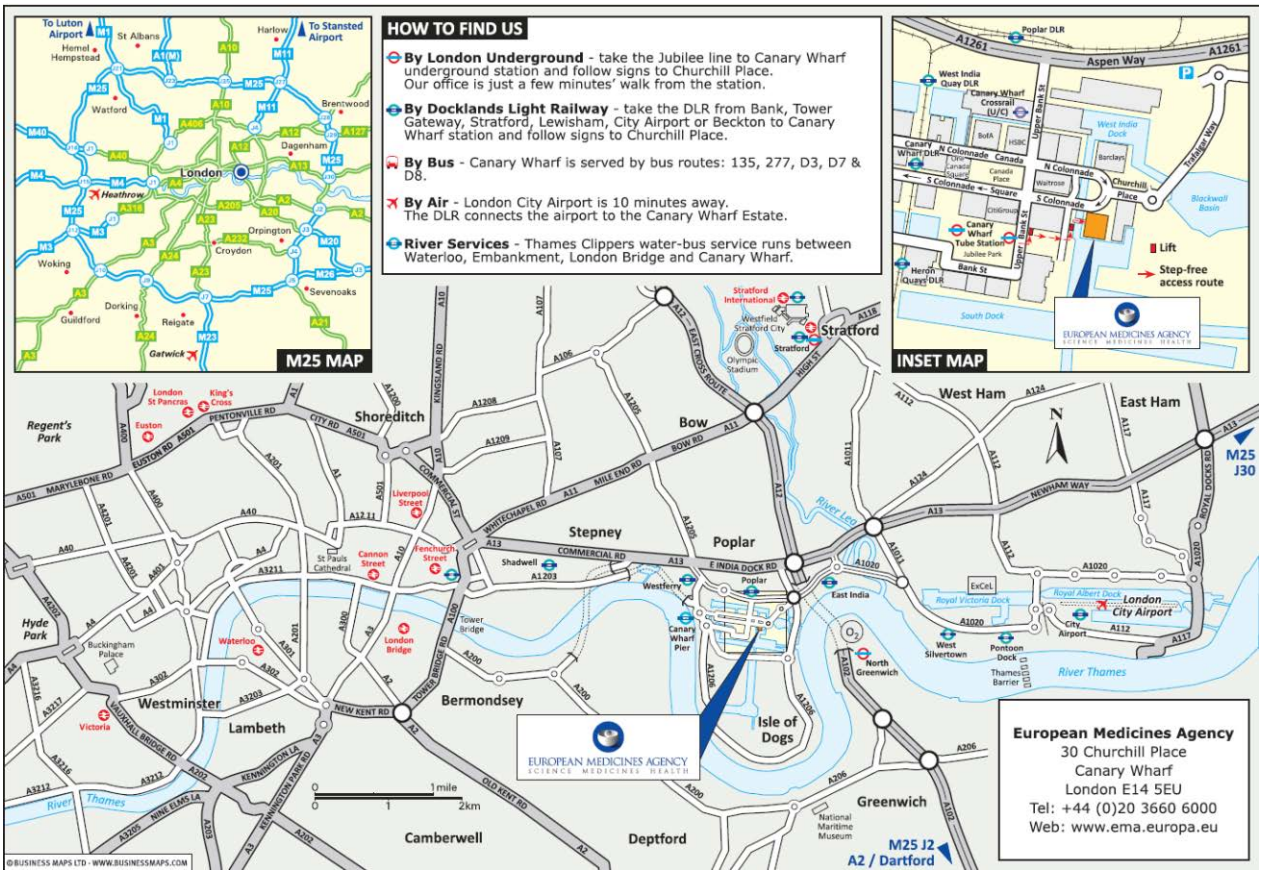
http://www.canarywharf.com/workwithus/The-Estate/Estate-Map/

Getting to Canary Wharf

The EMA is located in Canary Wharf, a business district in the east of London.

Please find below the public transport options for travelling to Canary Wharf together with the approximate journey times and the map of the area.

Directions to European Medicines Agency and map of the area



By Docklands Light Railway (DLR)

Both venues are a short walk from Canary Wharf or Heron Quays station on the DLR. Services run from Bank, Tower Gateway, Lewisham, Stratford, King George V and Beckton.

By Underground

The nearest stop for both venues 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 Bus

Canary Wharf is serviced by local bus numbers D3, D7, D8, 135 and 277.

River services

River services run between Embankment, London Bridge and Canary Wharf throughout the day. Canary Wharf pier is roughly a 15-minute walk from the European Medicines Agency.

From London City Airport

Take DLR City Airport to Canary Wharf (journey time is around 20 minutes).

From Gatwick Airport

Take a mainline train to London Bridge, then the Jubilee Line to Canary Wharf (journey time around 50 minutes).

From Heathrow Airport

Take the London underground Piccadilly Line to Green Park, change to the Jubilee Line to Canary Wharf (journey time around 1hr 20 minutes).

Alternatively, take the Heathrow Express train to Paddington, then the Circle or Bakerloo line to Baker Street, then the Jubilee Line to Canary Wharf (journey time around 1hr 20 minutes).

Alternatively, you can take the Heathrow Express train to Paddington, then the District or Circle Line to Tower Hill then the Docklands Light Railway (DLR) to Canary Wharf (journey time around 1hr 30 minutes).

From Stansted Airport

Take the Stansted Express to London Liverpool Street then the Circle Line to Tower Hill and change onto the DLR to Canary Wharf (journey time around 70 minutes).

From Luton Airport

Take a first Capital Connect train to London Bridge then the Jubilee Line to Canary Wharf (journey time around 60 minutes).

From St Pancras International train station

Take the Northern Line to London Bridge then the Jubilee Line to Canary Wharf (journey time around 45 minutes).

Contact

Should you have any questions, please contact Nadja Kriste or Milton Bonelli via SWP-H@ema.europa.eu

Useful links

http://www.tfl.gov.uk/

National Rail

Gatwick Express

Heathorw Express

Stansted Express

Eurostar

Heathrow airport

Gatwick airport

London City

London Stansted

Hillgate travel