



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 November 2017
EMA/CHMP/673240/2017
Human Medicines Research & Development Support Division

Workshop on Site and Histology – Independent Indications in Oncology

Programme

14-15 December 2017
European Medicines Agency, London, United Kingdom

Meeting **room 2F**



Programme details

Day Chair **Pierre Demolis**, *French National Agency for Medicines and Health Products Safety (ANSM)*

14 December 2017, 14:00-19:40

14:00-14:15 **Introduction**

Francesco Pignatti, *EMA*

14:15-15:40 **Session 1: Pharmacodynamics (1) - The driver**

Chair: **Spiros Vamvakas**, *EMA*

14:15-14:45 Definition of a driver.
Cellular/tissular mechanisms supporting that a driver becomes a target
Multiple drivers, mechanisms of resistance

Christian Rolfo, *Antwerp University*

14:45-15:30 Non-clinical models
Tumour models - proof of concept

Edward Rojsford, *Pfizer*

Proof of concept and regulatory considerations

Jan Willem van der Laan, *Medicines Evaluation Board (MEB)*

15:30-16:35 **Session 2: Pharmacodynamics (2) - Tumour sensitivity**

Chair: **Filip Josephson**, *Medical Products Agency (MPA)*

15:30-16:35 Parameters guiding site/histology independent drug development

Jan Schellens, *The Netherlands Cancer Institute*

The BRAF story

Yibing Yan, *Roche*

16:35-16:50 **Coffee Break**

16:50-17:40 **Session 3: Exploratory trials**

Chair: **Lothar Bergmann**, *Klinikum der Johann Wolfgang Goethe-Universität*

16:50-17:40 What is an exploratory development in a histology independent setting?
Differences and transition between exploratory / confirmatory trials

Richard Simon, *National Cancer Institute (NCI) (by Adobe)*

How could molecular profiling impact histology independent labels in the future?

Marlene Thomas, *Roche*

17:40–19:40 **Session 4: Confirmatory trials (1) – Population**

Chair: **Paolo Foggi**, *Agenzia Italiana del Farmaco (AIFA)*

17:40-18:20 What defines the disease and populations? How to deal with large subgroups and cancer within an indication? *Heterogeneity, lack of historical real-life data, rarest subtypes*

Jan Bogaerts, *European Organisation for the Research and Treatment of cancer (EORTC)*

18:20-18:35 Selection: Companion tests, validation. Prognostic value of the driver? Selection of the optimal cut-off for positivity, internal and external validation of its sensitivity / specificity.

Olivier Collignon, *EMA, Luxembourg Institute of Health*

18:35-18:50 Accuracy of diagnostic methods and impact on clinical management: the Lymphopath Network experience.

Philippe Gaulard, *Lymphoma Study Association (LYSA), France*

18:50-19:05 What have we learnt from the anti PD1- PDL1 story?

Complex cut-offs, downstream markers.

Jorge Camarero Jiménez, *Spanish Agency of Medicines and Medical Devices (AEMPS)*

19:05-19:30 Discussion

19:30–19:40 End of day – closing remarks

15 December 2017, 08:30-11:50

08:30-11:00 Session 5: Confirmatory trials (2) - Methodology and statistics

Chair **Olivier Collignon**, *EMA, Luxembourg Institute of Health*

08:30-09:30 Methodological considerations

Anja Schiel, *Norwegian Medicines Agency (NOMA)*

Olivier Collignon, *EMA, Luxembourg Institute of Health*

Definition of clear success criteria: How do we determine a trial is positive? Pooling of sub-studies

Robert Beckman, *Lombardi Comprehensive Cancer Center and Innovation Center for Biomedical Informatics*

09:30-09:50 Post-approval confirmatory / supplementary data:

Registries, observational trials, providing data on rarest subtypes, addressing uncertainties

Vincent Ho, *Integraal Kankercentrum Nederland (IKNL)*

09:50-10:05 Coffee break

10:05-10:45 Statistical planning of the Keytruda programme and interaction with the FDA

Lessons learnt and feedback from Merck

Steven Lemery, *Food & Drug Administration (FDA)*

Christine Gause, *Merck Sharp & Dohme (MSD)*

10:45-11:00 What is the HTA view?

Anja Schiel, *Norwegian Medicines Agency (NOMA)*

11:00-11:50 Wrap-up discussion

11:50-12:15 Coffee break

15 December 2017, 12:15 – 13:15 Panel discussion and close of the meeting

12:15-13:00 Panel discussion

Panel chair: **Jonas Bergh**, *Karolinska Institutet*

The clinicians' views; to what extent gene profiling and off-label use of targeted agents actually occurs

Clinical experience with Immunotherapy

The patients' views

Pierre Demolis, *French National Agency for Medicines and Health Products Safety (ANSM)*

Paolo Foggi, *Agenzia Italiana del Farmaco (AIFA)*

Rosa Giuliani, *European Society of Medical Oncology (ESMO)*

Patients' representatives (names tbc)

13:00 **Conclusions, closing remarks**

Pierre Demolis, *French National Agency for Medicines and Health Products Safety (ANSM)*

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 ONCWP@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

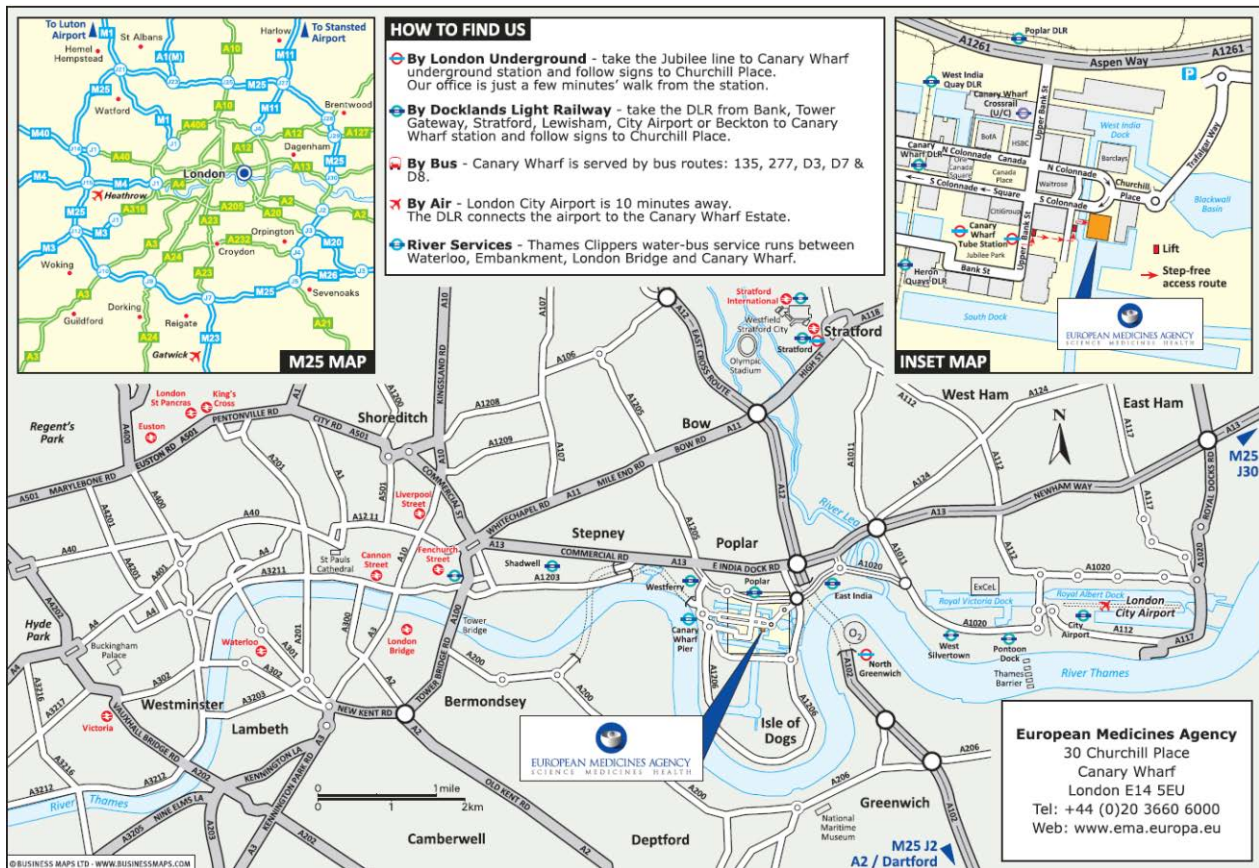
<http://www.canarywharf.com/workwithus/The-Estate/Estate-Map/>

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 Monica Simeoni or Kevin Blake via ONCWP@ema.europa.eu

Useful links

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

[National Rail](#)

[Gatwick Express](#)

[Heathrow Express](#)

[Stansted Express](#)

[Eurostar](#)

[Heathrow airport](#)

[Gatwick airport](#)

[London City](#)

[London Stansted](#)

[Hillgate travel](#)