



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 March 2017
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Corporate Stakeholders Department - SME Office

SME info day: The new clinical trial regulation

Monday, 20 March 2017
European Medicines Agency, London, United Kingdom



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Background and objectives

The landscape for the regulation of clinical trials in the European Union (EU) will undergo a major change when Clinical Trial Regulation EU No 536/2014 comes into operation in 2018. This info day will provide an overview of the key features of the new clinical trial regulation. It will also cover the future clinical trial authorisation process, the functionalities of the EU CT portal and database, transparency aspects and safety reporting requirements. Details about the future training programme will also be set out.

The event is open to companies that have been assigned SME status by the EMA and to representatives of stakeholder organisations. It will be broadcast and recorded for other interested parties to follow the proceedings.

Programme details

Monday, 20 March 2017, Meeting room 3A

09:00 Registration & coffee

09:30 Welcome and introduction

Ana Rodriguez Sanchez Beato, Head of Clinical and Non-Clinical Compliance (EMA) **10'**

09:40 Session 1: Overview of the clinical trial regulation

Key features and objectives of Regulation EU No 536/2014 - What is new, what has changed?

Laura Pioppo, Clinical & Non-clinical Compliance (EMA) **40'**

Questions and discussion **20'**

10:40 Coffee break

11:10 Session 2: The future clinical trial authorisation process

The new submission process

Tomáš Boráň, Head of Clinical Trials Unit, State Institute for Drug Control (SUKL) **30'**

The new evaluation process

Massimiliano Sarra, Italian Medicine Agency (AIFA) **30'**

Questions and discussion **20'**

12:30 Lunch break

13:30 Session 3: EU CT portal and database, transparency and safety reporting

EU CT Portal and Database**Noémie Manent**, Clinical & Non-clinical Compliance (EMA)**30'*****What is new in terms of transparency?*****Kevin Cunningham**, Clinical & Non-clinical Compliance (EMA)**20'*****Safety reporting requirements*****Sophia Mylona**, Clinical & Non-clinical Compliance (EMA)**15'*****Questions and discussion*****25'**

15:00 Session 4: A SME perspective on the implementation of the regulation

Kate Darwin, Trio Medicines Ltd**20'*****Questions and discussion*****20'**

15:40 Session 5: Future training program on the implementation of the clinical trial regulation

Ana Rodriguez Sanchez Beato, Head of Clinical and Non-Clinical Compliance (EMA)**15'*****Questions and discussion*****15'**

16:10 Closing remarks

Ana Rodriguez Sanchez Beato, Head of Clinical and Non-Clinical Compliance (EMA)

List of speakers

Ana Rodriguez Sanchez Beato	Head of Clinical and Non-Clinical Compliance (EMA)
Laura Pioppo	Clinical & Non-clinical Compliance (EMA)
Tomáš Boráň	Head of Clinical Trials Unit, State Institute for Drug Control (SUKL)
Massimiliano Sarra	Italian Medicine Agency (AIFA)
Noémie Manent	Clinical & Non-clinical Compliance (EMA)
Kevin Cunningham	Clinical & Non-clinical Compliance (EMA)
Sophia Mylona	Clinical & Non-clinical Compliance (EMA)
Kate Darwin	Trio Medicines Ltd

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)**

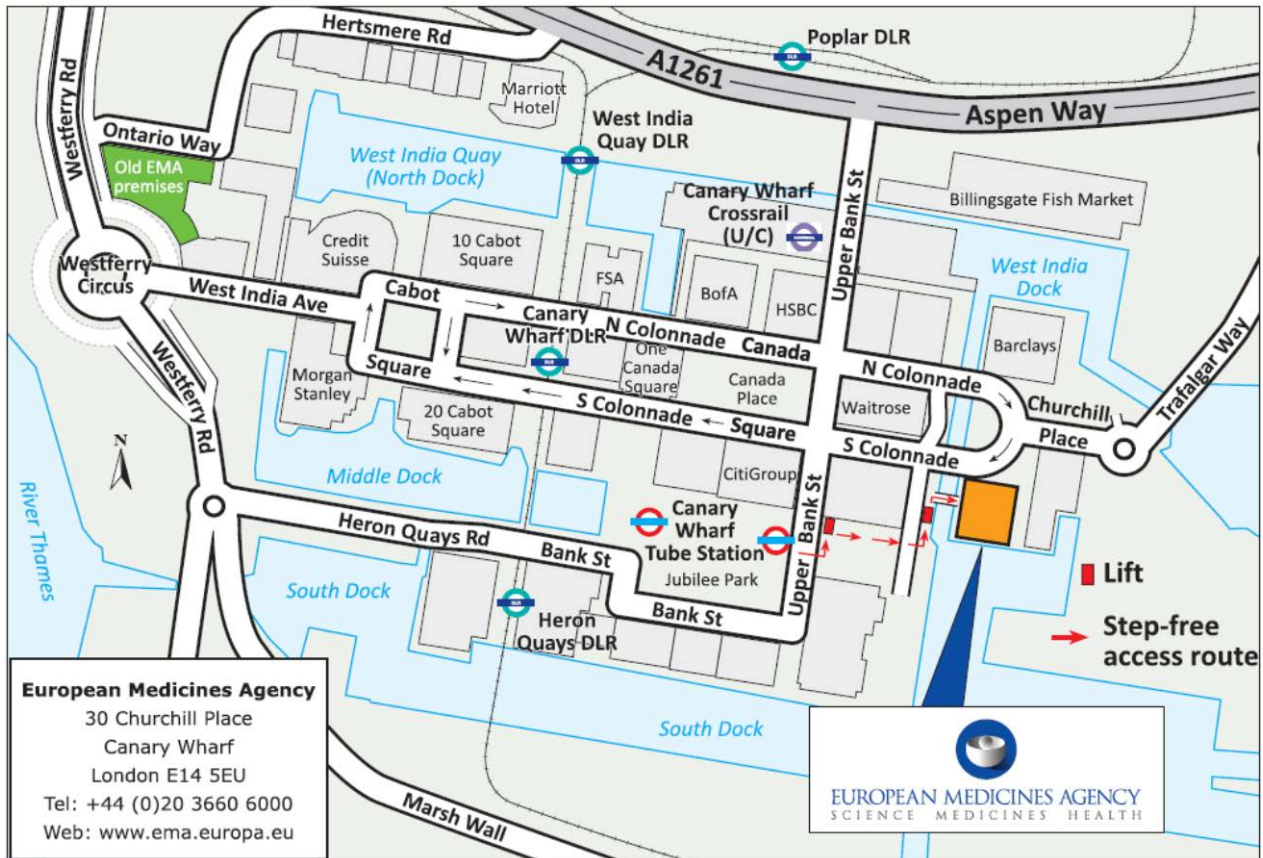
The Agency is a short walk from Canary Wharf station on the DLR. Services run from Bank, Tower Gateway, Lewisham, Stratford, King George V and Beckton. Exit into The South Colonnade, turn left towards Canada Square continuing straight into Churchill Place.

- **By car**

There are no parking facilities at 30 Churchill Place and it is recommended that you take public transport. However, four nearby public car parks are operated by Canary Wharf. Rates and further information can be found on the Canary Wharf website:

<http://canarywharf.com/getting-here/parking/>

Map



Arrival at the Agency

On arriving for your meeting at 30 Churchill Place, please report to reception where you will be issued with an access pass. This pass will allow you to access our industry lounge, which you are welcome to utilise during your visit. The industry lounge is located through the sliding doors to the right of the reception desk past the security turnstiles. Your EMA contact point will meet you here.

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

You will be able to sit wherever you wish; note that the only reserved seats are for the speakers, panellists and organisers of the workshop.

Presentations

We will not circulate printouts of speakers' presentations. However, you will be able to download them from the Agency's website approximately two weeks after the end of the workshop.

Wi-Fi access & Laptop computers

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

Media disclaimer

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Conference venue and secretariat

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