MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Data Anonymisation – a Key Enabler for Clinical Data Sharing

Workshop programme

30 November – 1 December 2017

Meeting Room 2/A (2nd Floor)

European Medicines Agency, London, United Kingdom

Multi-Regional Clinical Trials Center of Harvard and Brigham and Women's Hospital (MRCT Center)

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
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Background and objectives

Objectives of workshop:

- To propose guiding principles to enable international data sharing in the public interest
- Building on the platform of work by EMA, to review anonymisation approaches applicable to a broader set of data which ensure privacy protection and meet the standards required to maintain accessibility and the scientific utility of the data
- To examine opportunities for harmonisation of international clinical data sharing, taking into consideration data protection in the different jurisdictions.

Scope:

- Clinical trial data and real world data (in the context of patient registries and individual cohort studies)

Out of Scope:

Whilst recognising that there is a continuum of data ranging from clinical trials through to social media, and that principles agreed for clinical trials will be relevant for other types of data, there will be no recommendations for the following:

- Electronic medical records
- Claims / administrative health records
- Social media data
- Mobile health data

Outputs:

- A report describing a clear set of recommendations

List of speakers and moderators

Ada Adriano	European Medicines Agency (EMA)
Barbara Bierer	MRCT Center, Harvard
Janice Branson	Novartis
Alison Cave	European Medicines Agency (EMA)
Robyn Challinor	European Young Persons' Advisory Groups Network (eYPAGnet)
Isabelle Chatelier	DG Justice and Consumers, European Commission
Monica Dias	European Medicines Agency (EMA)
Khaled El Emam	Real World Evidence Solutions
Mark Elliot	Manchester University
François Houÿez	Eurordis
Robert Kristof	Gamian-Europe
Pierre-Yves Lastic	Sanofi-Aventis
Rebecca Li	MRCT Center, Harvard and Vivli
Brad Malin	Vanderbilt University
Edwin Morley-Fletcher	MyHealthMyData (MHMD) H2020 Project
Jennifer O'Callaghan	Wellcome Trust
Christian Ohmann	European Clinical Research Infrastructure Network (ECRIN)
Frank Pétavy	European Medicines Agency (EMA)
Karen Quigley	European Medicines Agency (EMA)
Guido Rasi	European Medicines Agency (EMA)
Liz Roberts	TransCelerate
Frank Rockhold	Duke University
Joseph Ross	Yale University
Tomas Salmonson	Committee for Medicinal Products for Human Use (CHMP)
Brian Shand	Public Health England
Fergus Sweeney	European Medicines Agency (EMA)
David Townend	Maastricht University
Irina Vasiliu	DG Justice and Consumers, European Commission
Effy Vayena	ETH Zurich

Programme Details

Thursday, 30 November 2017

12.30 Registration

The workshop will be held in room 2A. Please collect badges at the reception on the ground floor.

13:00 Welcome and introduction

Guido Rasi, Executive Director, EMA ***10'***

13:10 Session 1: Setting the scene

Chair: Fergus Sweeney, Head of Division, Inspections, Human Medicines Pharmacovigilance and Committees, EMA

Objectives of the session:

- *To describe the global landscape and highlight challenges for international clinical data sharing.*
- *To describe the current EMA guidance and its key recommendations highlighting the successes and challenges encountered during the implementation of Phase 1 of Policy 0070.*
- *To understand the legislation impacting clinical data sharing across two jurisdictions, drawing out differences and similarities.*
- *To propose guiding principles to enable international data sharing in the public interest.*

Keynote lecture: The Global Landscape in Clinical Data Sharing ***25'+5'***

Speaker: Barbara Bierer (Faculty Director, MRCT Center, Harvard, USA)

Regulatory Perspective – current EMA external guidance on anonymisation – successes and future challenges ***25'+5'***

Speaker: Frank Pétavy (Head of Biostatistics and Methodology Support, EMA)

Defining the legislation which directly impacts on clinical data sharing ***60'***

Speakers: Irina Vasiliu, Isabelle Chatelier, European Commission (joining via Video Conference), Barbara Bierer (Faculty Director, MRCT Center, Harvard, USA)

Agree key messages/points ***10'***

15:20 Coffee break

15:45 Session 2: The Foundation of Data Anonymisation

Chair: Monica Dias, Crisis Coordinating Officer / Policy Officer, EMA

Objectives of Session:

- *To define and critique the key concepts which must be considered from a technical (methodological) and legal perspective.*
- *To discuss how the balance between data anonymisation and scientific utility can be achieved.*
- *To consider how the context of the disease affects the risk-based approach.*
- *To draw out any international differences.*

Functional Anonymisation and the Data Environment ***30'***

Speaker: Mark Elliot (Manchester University)

Risk-based approaches for data anonymisation ***25'***

Speaker: Khaled El Emam (Director, Real World Evidence Solutions)

How does consent influence the data anonymization approach and data sharing across different regulatory jurisdictions? ***25'***

Speaker: David Townend (Maastricht University)

Defining sensitive data – influence of the context of the disease on the tolerability of risk ***45'***

Speakers: François Houÿez (Eurordis), Robert Kristof (Gamian-Europe), Robyn Challinor, European Young Persons' Advisory Groups Network (eYPAGnet)

General questions to patient representatives ***10'***

Discussion session with discussants from the audience ***60'***

19:00 **End of Day 1**

Friday, 1 December 2017

08:15-08:30 Coffee and pastries

08:30 Session 3: The mechanics of anonymisation – meeting the challenge of different data

Chair: Karen Quigley, Clinical Data Publication Manager, EMA

Objectives of the session:

- *Building on the principles defined in Session 2, to define strengths and limitations of current methodology keeping scientific utility in mind and considering the international perspective.*
- *To illustrate the challenges of the technological approaches with concrete case examples.*
- *To discuss whether anonymisation techniques are equivalent across different data sets.*

Summary of Day 1 ***10'***

A review of anonymisation techniques – strengths and limitations of different methods across different jurisdictions ***25'***

Speaker: Brad Malin (Vanderbilt University)

Comparison of anonymisation techniques in the context of clinical study reports – Advantages and disadvantages of different approaches ***25'***

Speaker: Ada Adriano (EMA)

Anonymisation techniques in context of individual patient level data ***40'***

Speaker: Janice Branson (Novartis), Pierre-Yves Lastic (Sanofi-Aventis)

Does one size fit all? – Challenges of anonymising real world data ***25'***

Speaker: Brian Shand (Public Health England)

Questions on presentations and general discussion ***15'***

Define actions and next steps around broader data sharing ***10'***

11:00 Coffee break

11:20 Session 4: Balancing access and data utility

Chair: Rebecca Li, MRCT Center, Harvard and Vivli

Objectives of Session:

- *To define how different mechanisms of access (from open access to a range of controlled access mechanisms) influence anonymisation approaches and ultimately data quality.*
- *To consider challenges for operationalising clinical data sharing.*
- *To discuss the challenges for accessing and analysing data from the user perspective*

Overview of data sharing possibilities to faciliate international data sharing ***15'***

Speaker: Rebecca Li (MRCT Center, Harvard and Vivli)

Panel session involving representation ***75'***

Panel:
- Jennifer O'Callaghan (Wellcome Trust)
- Christian Ohmann (European Clinical Research Infrastructure Network (ECRIN))
- Liz Roberts (TransCelerate)
- Frank Rockhold (Duke University)
- Joseph Ross (Yale University)
- Tomas Salmonson (Chair CHMP, MPA, Sweden)

12:45-13:45 Lunch – Finger buffet outside of meeting room 2 / A

13:45 Session 5: Future Challenges for Data Anonymisation

Chair: Barbara Bierer, Faculty Director, MRCT Center, Harvard

Objectives of Session:

- *To consider how anonymisation approaches can keep pace with the evolving scientific landscape.*
- *To consider what additional challenges will be posed by linking multiple datasets eg genomic and healthcare data and the challenges raised by new innovative datasets.*
- *To discuss how anonymisation approaches can be future-proofed.*

Influence of changing scientific landscape on data protection ***25'+5'***

Speaker: Effy Vayena (ETH Zurich)

Encryption, Anonymisation, and Artificial Intelligence ***25'+5'***

Speaker: Edwin Morley-Fletcher (MyHealthMyData (MHMD) H2020 Project)

14:45 Final Discussion

Agreement on a clear set of recommendations

Speaker: EMA + MRCT

Key messages and conclusions

Speaker: EMA + MRCT

Closing remarks

Speaker: Fergus Sweeney, EMA

16:30 End of the workshop

	First Name	Last Name	Job Title	Affiliation
1.	Ada	Adriano	Access to Documents Manager	European Medicines Agency
2.	Davide	Ajello	Compliance Manager	Menarini Group (representing EFPIA)
3.	Enrica	Alteri	Head of Division, Human Medicines Research & Development Support	European Medicines Agency
4.	Arturo	Alvarez-Gutierrez	IT Manager & CDO	Spanish Medicines Agency (AEMPS), Spain
5.	Regina	Becker	Scientific Support Staff Member	Luxembourg University, Luxembourg
6.	Janis	Bernat	Director, Biotherapeutics & Scientific Affairs	International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), Switzerland
7.	Barbara	Bierer	Faculty Director	Multi Regional Clinical Trials (MRCT) Center, Harvard, USA
8.	Sergio	Bonini	Associate Researcher	Italian National Research Council, Italy
9.	Barbara	Bovy	QPPV	Mithra Pharmaceuticals (representing Eucope)
10.	Janice	Branson	Head of Statistics, Immunology and Dermatology Franchise	Novartis
11.	Sabine	Brosch	Business Lead, EudraVigilance and International Standardisation in Pharmacovigilance	European Medicines Agency
12.	Francesca	Cattarin	Health Policy Officer	Bureau Européen des Unions de Consommateurs (BEUC), Belgium
13.	Alison	Cave	Principal Scientific Administrator	European Medicines Agency
14.	Robyn	Challinor	Young Patient Research Ambassador	European Young Persons' Advisory Groups Network (eYPAGnet), UK
15.	Isabelle	Chatelier	Legal and Policy Officer	European Commission – DG Justice and Consumers (JUST.C.3.), Belgium
16.	Anne	Cutting	Director, Clinical Data Transparency	GlaxoSmithKline (representing Vaccine Europe)
17.	Giuseppe	D'Acquisto	Technology Adviser	Data Protection Authority, Italy
18.	William	Davidson	Joint Head of Policy	Health Research Authority, UK
19.	Corinne	de Vries	Head of Science and Innovation Support Office	European Medicines Agency
20.	Monica	Dias	Policy and Crisis Coordinating Officer	European Medicines Agency
21.	Axel	Diefenbach	Global Data Privacy Business Partner Research & Development	Bayer
22.	Falk	Ehmann	Scientific Administrator, Human Medicines Research and Development Support – Science & Innovation Support	European Medicines Agency
23.	Khaled	El Emam	Director	Real World Evidence Solutions, Canada
24.	Mark	Elliot	Professor of Data Science	Manchester University, UK
25.	Sini	Eskola	Regulatory Affairs Director	European Federation of Pharmaceutical Industries and Associations (EFPIA)
26.	Jean-Marc	Ferran	Consultant and Owner Data Transparency Working Group Lead	Qualiance PhUSE

27.	Uwe	Fiedler	Chief Privacy Officer & Vice-President DP	PAREXEL International
28.	Laura	Flannery	Lead Consultation Specialist	Office of the Data Protection Commissioner, Ireland
29.	Christine	Fletcher	Executive Director Biostatistics	Amgen
30.	Cathal	Gallagher	Life Science Consultant	d-Wise
31.	Katie	Gallagher	Policy Adviser	European Patients' Forum, Belgium
32.	Juan	Garcia	Head of Medical and Health Information	European Medicines Agency
33.	Rolf	Gedeborg	Scientific Director, Epidemiology and Pharmacovigilance	Medical Products Agency, Sweden
34.	Carlo	Giaquinto	Director, Paediatric and neonatal Infectious Disease Unit / Paediatric Clinical Research Unit of the Department of Paediatrics	Padova University, Italy
35.	Claire	Gayrel	Legal Officer	European Data Protection Supervisor, Belgium
36.	Anne-Sophie	Henry-Eude	Head of Section for Documents Access and Publication	European Medicines Agency
37.	Julie	Holtzople	Clinical Trial Transparency Operations Director	AstraZeneca (representing Vaccine Europe)
38.	Paul	Houston	European CDISC Liaison	Clinical Data Interchange Standards Consortium (CDISC), USA
39.	François	Houyez	Director of Treatment Information and Access, Policy Advisor	Rare Diseases Europe (EURORDIS), France
40.	Leah	Isakov	Global Head of Bio-Statistics, Data Management, Programming and Medical Writing	Seqirus (representing Vaccine Europe)
41.	Melanie	Jones	Senior Manager, Biostatistics and Statistical Programming	Covance (representing ACRO)
42.	Dipak	Kalra	President	European Institute for Health Records, France
43.	Kostoula	Kampouraki	IT Policy Administrator	European Data Protection Supervisor, Belgium
44.	Peter	Kearney	Chair of the ESC Advocacy Committee	European Society of Cardiology
45.	Lukasz	Kniola	Principal Analyst/Data Sharing	Biogen
46.	Hideyuki	Kondo	Deputy Director, Office of International Programs	Pharmaceuticals and Medical Devices Agency (PMDA), Japan
47.	Desislava	Krasimirova-Borisova	Data Protection Specialist	European Union Agency for Law Enforcement Cooperation (Europol), The Netherlands
48.	Robert	Kristof	General Manager of Awakening Foundation	Gamian Europe
49.	Karmela	Krleza-Jeric	Principal investigator/IMPACT Observatory	Ottawa Group-IMPACT, Canada & MedILS, Croatia (representing CORBEL)
50.	Jenny	Krutzinna	Postdoctoral Researcher in the Ethics of Biomedical Big Data	Oxford Internet Institute, Oxford University, UK
51.	Xavier	Kurz	Head of Surveillance and Epidemiology Service	European Medicines Agency
52.	Sandra	Kweder	Liaison Official	US FDA

53.	Pierre-Yves	Lastic	Associate Vice-President, Chief Privacy Officer	Sanofi
54.	Nathan C.	Lea	Senior Research Associate	University College London, Institute of Health Informatics (IHI), UK
55.	Rebecca	Li	Executive Director	Multi Regional Clinical Trials (MRCT) Center, Harvard and Vivli, USA
56.	Charles	Liss	Associate Director, Statistical Science	CSL Behring (representing Eucope)
57.	Michele	Loi	Postdoctoral Researcher in the Ethics of Biomedical Big Data	Department of Informatics, Institute of Biomedical Ethics & History of Medicine, Zurich University, Switzerland
58.	Elaine	Mackey	Research Associate	Manchester University, UK
59.	Brad	Malin	Professor of Biomedical Informatics, Biostatistics and Computer Science –	Vanderbilt University, USA
60.	Noemie	Manent	Business Lead, Support the Implementation of the Clinical Trials Regulation	European Medicines Agency
61.	Friedrich	Maritsch	Lead Data Anonymisation in Clinical Trial Transparency	Shire
62.	Dirk	Mentzer	Chair, EMA Paediatric Committee (PDCO)	Paul-Ehrlich Institute, Germany
63.	Brent	Mittelstadt	Research Fellow	The Alan Turing Institute, UK
64.	André	Molgat	Regulatory Affairs Officer	Health Canada, Canada
65.	Edwin	Morley-Fletcher	President	Lynkeus srl (representing MyHealthMyData (MHMD) H2020 Project)
66.	Miranda	Mourby	Researcher in Law	Centre for Health, Law and Emerging Technologies, Oxford University, UK
67.	Valerie	Muldoon	EMA Secretariat	European Medicines Agency
68.	Sarah	Nevitt	Research Assistant	Liverpool University, UK
69.	Victoria	Newbould	Scientific Administrator	European Medicines Agency
70.	Jennifer	O' Callaghan	Clinical Data Sharing Manager	Wellcome Trust, UK
71.	Christian	Ohmann	Consultant	European Clinical Research Infrastructure Network (ECRIN) Düsseldorf, Germany
72.	Nicola	Orlandi	Head Data Privacy Pharma	Novartis
73.	Marisa	Papaluca	Senior Scientific Adviser	European Medicines Agency
74.	Lee	Parker	Director, Data Privacy Europe and Canada	Biogen
75.	Anna Maria Gerdina	Pasmooij	Project Leader Patient-Oriented Evaluation and Clinical Assessor	Dutch Medicines Evaluation Board, The Netherlands
76.	Frank	Pétavy	Head of Biostatistics and Methodology Support	European Medicines Agency
77.	Francesco	Pignatti	Head of the Office of Oncology, Haematology and Diagnostics	European Medicines Agency
78.	Marie-Hélène	Pinheiro	Industry Stakeholder Liaison	European Medicines Agency
79.	Neil	Pratt	Assistant General Counsel	PhRMA, USA
80.	Jennifer	Preston	Patient and Public Involvement & Engagement Priority Lead	NIHR Clinical Research Network Coordinating Centre, Liverpool University, UK

81.	Karen	Quigley	Clinical Data Publication Manager	European Medicines Agency
82.	Veronica	Quinto	EMA Secretariat	European Medicines Agency
83.	Guido	Rasi	Executive Director	European Medicines Agency
84.	Liz	Roberts	Senior Director, Global Lead Transparency and Data Sharing	UCB (representing TransCelerate)
85.	Frank	Rockhold	Professor of Biostatistics & Bioinformatics	Duke Clinical Research Institute, USA
86.	Joseph	Ross	Associate Professor of Medicine (General Medicine)	Yale School of Medicine, USA
87.	Paolo	Rossi	Professor and Chairman, Dept. of Paediatrics	Rome University Tor Vergata, Italy
88.	Benjamin	Rotz	Director of Medical Transparency	Eli Lilly (representing Transcelerate)
89.	Cathal	Ryan	Assistant Commissioner	Office of the Data Protection Commissioner, Ireland
90.	Agnès	Saint-Raymond	Head of International Affairs	European Medicines Agency
91.	Adel Ezzo	Salem	Programming Specialist	Novo Nordisk (representing EFPIA)
92.	Tomas	Salmonson	Chair, EMA Committee for Medicinal Products for Human Use (CHMP)	Medical Products Agency, Sweden
93.	Ancel.la	Santos Quintano	Senior Policy Advisor, European Union Projects	Health Action International, The Netherlands
94.	Kanako	Sasaki	Assistant Director	Ministry of Health, Labour and Welfare - Government of Japan, Japan
95.	Anja	Schiel	Chair, EMA Biostatistics Working Party	Norwegian Medicines Agency, Norway
96.	Brian	Shand	Information Security Architect	Public Health England, UK
97.	Olivia	Shopshear	Director, Science and Regulatory Advocacy	PhRMA, USA
98.	Fernando	Silva	Data Protection Officer	eu-LISA, Estonia
99.	Alessandro	Spina	EMA Data Protection Officer	European Medicines Agency
100.	Stefan	Strasser	Deputy Head of Department	Austrian Agency for Food and Health Safety (AGES), Austria
101.	Thordur	Sveinsson	Legal Counsel	Data Protection Authority, Iceland
102.	Kristian	Svendsen	Researcher	UiT, The Arctic University of Norway
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104.	Rafal	Świerzewski	Associate Consultant	European Cancer Patient Coalition (ECPC), Belgium
105.	David	Townend	Professor of Law and Legal Philosophy in Health, Medicine and Life Sciences	Maastricht University, The Netherlands
106.	Katherine	Tucker	Senior Manager, Data Sharing Lead	Roche
107.	Mark	Turner	Senior Lecturer in Neonatology (Clinical)	Liverpool University, UK
108.	Spiros	Vamvakas	Head of Section for Scientific Advice, Human Medicines Special Areas	European Medicines Agency

109.	Peter	Van Reusel	European CDISC Liaison	Clinical Data Interchange Standards Consortium (CDISC), USA
110.	Irina	Vasiliu	Team Leader	European Commission, DG Justice and Consumers (JUST.C.3.), Belgium
111.	Eftychia	Vayena	Professor of Bioethics	ETH Zurich, Switzerland

Directions to the EMA

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**

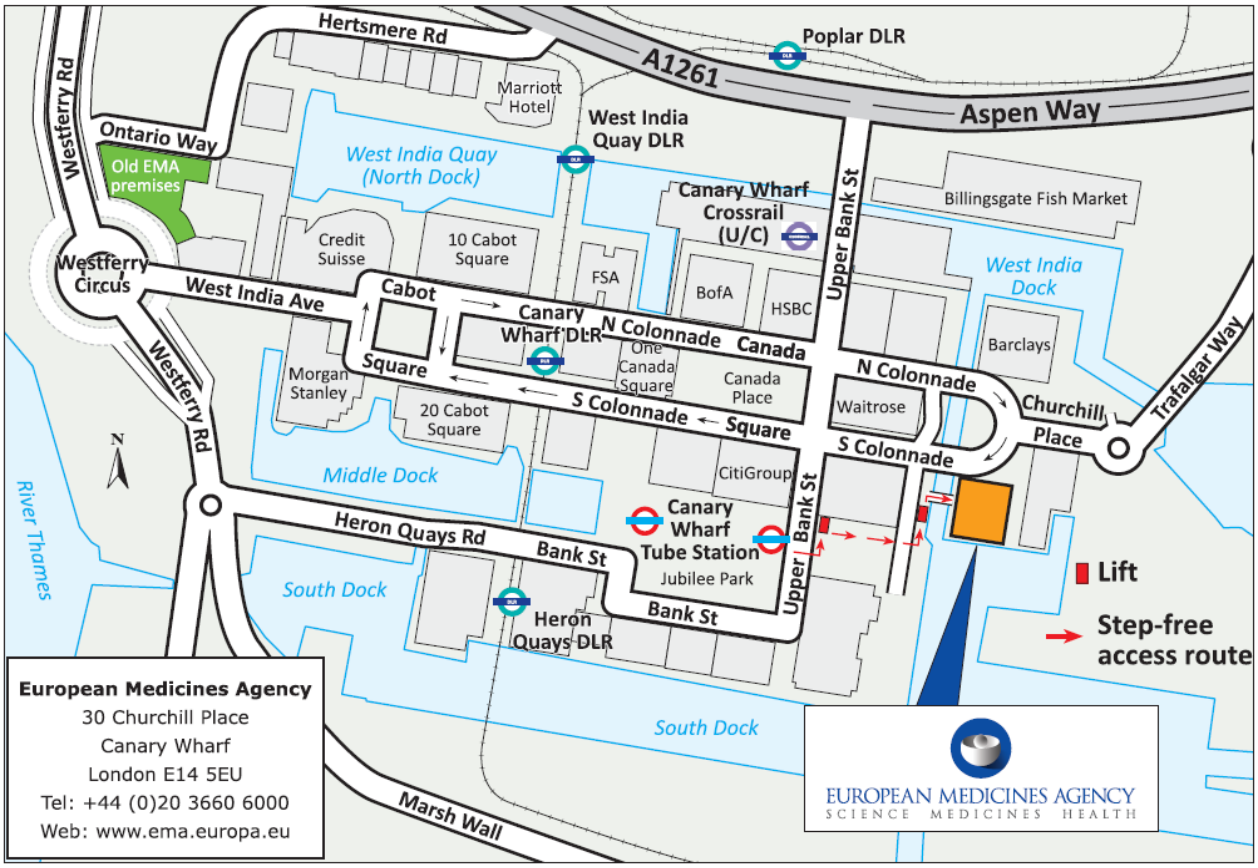
  There are no parking facilities at 30 Churchill Place and it is recommended that you take public transport. However, four nearby public car parks are operated by Canary Wharf. Rates and further information can be found on the Canary Wharf website: http://www.canarywharf.com/aboutus/The-Estate/Travel-/Roads--Parking/
- **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**

  The European Medicines Agency is a 10-minute walk from Blackwall or Poplar station on the DLR. Alternatively, change at Canning Town to the Jubilee Line to Canary Wharf station.

Map



Arrival at the Agency

Upon arrival at 30 Churchill Place, please report to reception where you will be issued with an access pass. The Agency requires that all visitors provide a valid photo ID, such as a Passport, National Identity Card, or a Driving Licence. **N.B. for security reasons, it is very important that the name on your valid photo ID is exactly identical to the name we have registered for you on our list of participants. Without an exact name match, participants may be turned away from the event**. 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.

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.

Meeting venue and secretariat

European Medicines Agency

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