European Innovation Council

31ST JANUARY 2023

EIC – EMA INFO DAY:
Regulatory support for the development of innovative medicines and technologies

AGENDA

The Info Day will provide an overview of the range of support that innovators in the pharmaceutical sector can access at the European Medicines Agency (EMA) to optimise their development programmes. It highlights platforms for early regulatory dialogue, the Priority Medicines (PRIME) scheme and Scientific Advice. The Info Day is targeted at EIC-funded beneficiaries and it is also open to beneficiaries of other EU programmes for research and innovation in the pharmaceutical and med-tech sectors. It will be broadcasted on YouTube and recorded for interested parties to follow the proceedings. Information about the Info Day can be found in the related event page.

MODERATORS:

Barbara Gerratana
Programme Coordination Manager, EIC Pathfinder Programme, EISMEA

Tony Humphreys
Head of the Regulatory Science and Innovation Taskforce, European Medicines Agency, EMA

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

09:00 – 09:10

Welcome addresses

Jean David Malo
EISMEA Executive Director

Emer Cooke
EMA Executive Director

09:10 – 09:30

Opening remarks by EIC Programme Managers

Iordanis Arzimanoglou
EIC Health and Biotech Programme Manager

Enrique Claverol Tinture
EIC MedTech Programme Manager

09:30 – 10:05

An overview of EMA development support to innovative medicines and technologies - Q&A

This session will provide an overview of EMA mandate and its role in supporting research and innovation in the pharmaceutical and MedTech sectors. Details will be provided on the range of R&D support services to academic researchers and SMEs, dedicated contact points, specific services targeting gene & cell therapies, orphan medicines and support by EMA's SME office.

Leonor Enes
Scientific Officer, SME Office, Regulatory Science and Innovation Task Force, European Medicines Agency, EMA

10:05 – 10:40

Innovation Task Force Services (ITF) - Q&A

This session will cover the role of ITF services in early regulatory dialogue and support to innovators, with examples of types of advice which can be sought on medicines, devices and technologies, as well as practical details on how to apply.

Falk Ehmann
Scientific Officer, Regulatory Science and Innovation Task Force, EMA

10:40 – 10:50

Testimonial on Innovation Task Force Services (ITF) - Q&A

Prof. BALAZ will share his experience with the Innovation Task Force Services (ITF) and will explain its impact on the project EVO-NANO.

Igor Balaz
Professor of Biophysics at the University of Novi Sad (Serbia) and coordinator of the EIC Pathfinder project EVO-NANO.

10:50 – 11:00

Break

11:00 – 11:30

Priority Medicines Scheme (PRIME) - Q&A

This session will highlight key benefits of the scheme in supporting medicines developments that address unmet medical needs, eligibility criteria, and how to prepare and submit a robust PRIME application.

Kevin Cunningham
PRIME Scientific Coordinator, Human Medicines Division, European Medicines Agency, EMA

Spiros Vamvakas
Scientific Adviser on Human Medicines, Human Medicines Division, EMA

11:30 – 12:00

EMA Scientific Advice - Q&A

This session will provide information on the range of advice available to academic researchers and SMEs including initial and follow-up advice, biomarkers qualification, parallel advice with the Food and Drug Administration (FDA) and Health Technology Assessment bodies (HTA). There will be examples of questions and topics raised on pharmaceutical, non-clinical and clinical developments. This session will also explain how to prepare a robust application and will provide recommendations and tips to facilitate its submission.

Iordanis Gravanis
Head of the Scientific Advice Office, Human Medicines Division , European Medicines Agency

12:00- 12:10

Testimonial on Scientific Advice - Q&A

AbilityPharma of EIC Accelerator project PanC-ASAP will share its experience with Scientific Advice.

Gemma Fierro
VP Clinical & Regulatory Affairs, AbilityPharma

Carles Domenech
CEO, AbilityPharma

12:10 – 12:25

The parallel journeys from Academia to Enterprise & from ITF to Scientific Advice - Q&A

Piotr Trzonkowski will share his experience in establishing an academic spin-off company and using EMA services such as ITF, EMA's advanced therapies classification and certification, and scientific advice.

Piotr Trzonkowski, *CEO PolTREG and TREG Accelerator project coordinator.*

12:25 – 12:30

Closing remarks by moderators Barbara Gerratana and Tony Humphreys