

# Expanded Access Programmes

Compassionate Use Programme (CUP) and Named Patient Programme (NPP) - practical know-how for you!

## TOPICS

- Matching the programme and the company strategy
- Programme design: CUP and NPP
- Medical governance and programme integrity
- From early access to regular launch: transitional plan, pricing, supply chain

## YOUR SPEAKERS



**Dr Marc Christian Bauer**  
Nektar Therapeutics Inc.



**Sarah Moore**  
GSK Global Medical Affairs  
Oncology



**Dr Stuart Bell**  
Inceptua Limited

## Expanded Access Programmes

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### Aims and objectives

Are you about to decide whether an expanded access programme should be developed or are you already about to plan and execute one? Then, this seminar supports you with legal and medical know-how. After having attended the seminar you know what to bear in mind in the planning phase, have received practical tips on how to do the medical oversight and how to determine a potential programme end.

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### Who should attend?

This seminar will provide in-depth information on CUPs and NPPs to all involved in clinical affairs, medical affairs, health technology assessment (HTA) and healthcare management, particularly those who develop, plan and conduct expanded access programmes.

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### Quality guaranteed!

We follow the IMI quality criteria and, as a signatory, we are an active partner in further developing and optimising the quality standards.

An aggregate evaluation of participants' feedback on all FORUM's healthcare training courses (evaluation period from 01.2021 -12.2021) produced a result of 1.8 (based on a school grading system of 1-6).

### YOUR SPEAKERS

#### Dr Marc Christian Bauer

Nektar Therapeutics Inc.

Vice President, Head of Operations Europe

#### Dr Stuart Bell

Inceptua Limited

Vice President Consulting, Early Access

#### Sarah Moore

GSK Global Medical Affairs Oncology

Research Director, Solid Tumors/Cell & Gene Therapy

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### Your benefits

- Three experts with extensive experience in setting up and conducting expanded access programmes
- A direct comparison between CUPs and NPPs
- Strategic information on country selection, outcome research possibilities and much more
- Use of live engagement tools to ensure a sustainable learning effect
- Interaction with other participants in the breaks
- Bringing participants across Europe together

# Compassionate use programme and named patient programme

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## Your programme 09:00 - 17:00

09:00 *Introduction*

09:15

### **Introduction and decision tree - matching the programme and the company strategy**

Dr Marc Christian Bauer

- Why set up a programme? Pros and cons
- Legal framework and preconditions: unmet medical need
- Named Patient Programme (NPP)
- Compassionate Use Programme (CUP)
- All the EU, CH, UK or specific countries?
- Should supply be free of charge or against payment?
- Exercise: Pros and cons of a programme

10:30 *Coffee break and time for discussion*

10:50

### **Early access programme design**

Dr Stuart Bell

- Intentions behind the programme
- Regulatory pathway selection
- Time frame and duration
- Infrastructure and logistics: Should a partner be involved?
- Costs and results
- Project planning
- Starting point and timing
- Outcomes research in EAPs: HTA in the focus, too?
- Exercise: An early access approach from the perspective of a small EU biotech company

12:10 *Lunch break*

13:10

### **Medical oversight and implementing early access programmes**

Sarah Moore

- Medical governance and programme integrity
- The challenges of execution
- Strategies and tools to maximise success
- Partnering with an access vendor
- Pharmacovigilance obligations and best practice

14:30 *Coffee break and time for discussion*

15:00

### **Should the programme end? From early access to regular launch**

Dr Marc Christian Bauer

- Unlimited programmes versus programmes that end with the marketing authorisation - consequences
- From early access to regular launch: transitional plan, pricing, supply chain

16:15 *Final discussion*

17:00 *End of seminar*

## Expanded Access Programmes

### REGISTRATION UNDER

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### REGISTRATION FORM

Yes, I will attend

☐ Expanded Access Programmes

☐ Yes, I agree that FORUM Institut may inform me about events by:  
☐ email; and/or ☐ telephone.  
I may withdraw my consent at any time.

#### Date

Thursday, 22 September 2022

Online from 09:00 - 17:00

You may dial in 30 min. before the session

#### Fee

€ 1090.00 (+ German VAT)

The fee includes a comprehensive online documentation and a certificate.

Name

Position, department

Company

Street

Post code, city, country

Tel. no./Fax no.

E-mail

Contact person at office

Date, signature

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- They are held and controlled directly by our speakers.
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- You will see the presentation and listen to our speaker's lecture using Internet telephony (VoIP) or even a normal telephone connection.
- And you can also ask questions live.

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### YOUR CONTACT



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