

# ExpertFORUM Labelling

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Online conference on current labelling topics

## TOPICS

- Preparation on ePI in pharmaceutical companies
- Insights from the IMI Gravitade-Health project
- Labelling supported by artificial intelligence (AI)
- Updates from the QRD group
- The future of labelling and labelling management

## YOUR SPEAKERS

### Dr Giovanna Ferrari

Pfizer Ltd.,  
Tadworth, GREAT BRITAIN

### Dr Niklas Jänich

Boehringer Ingelheim International GmbH,  
Ingelheim, GERMANY

### Tris Nockles

Navitas Life Sciences Limited,  
Portsmouth, GREAT BRITAIN

### Julian Backhouse

Regulatory Affairs and Labelling Consultant,  
Liverpool, GREAT BRITAIN

### Nina Malvik

Norwegian Medicines Agency,  
Oslo, NORWAY

## Aims and objectives

This ExpertFORUM focuses on the digitalisation of labelling, the transformational potential of emerging technologies like AI and how pharma companies need to prepare to implement these technologies.

European authority and industry experts will provide background information on ePI and AI, as well as practical insights from pilot projects such as the EMA ePI pilot and the IMI Gravitare-Health project.

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## Who should attend?

This online conference addresses the needs of individuals in regulatory affairs, medical affairs and pharmacovigilance involved in product information.

It provides useful updates on the relevant trends in labelling. A working knowledge of product information and labelling is required.

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## Your benefits

This ExpertFORUM will give you the opportunity to

- meet leading authority and industry experts.
- obtain first-hand insights into recent developments on ePI.
- learn about trends in labelling especially focussing on the use of AI.

## YOUR SPEAKERS



**Dr Giovanna Ferrari**

Pfizer Ltd.,  
Tadworth, GREAT BRITAIN

Senior Director and Project Lead for Gravitare Health



**Dr Niklas Jänich**

Boehringer Ingelheim  
International GmbH,  
Ingelheim, GERMANY

Head of Global Labeling Operations & Digitization



**Tris Nockles**

Navitas Life Sciences Limited,  
Portsmouth, GREAT BRITAIN

Regulatory Nets Lead



**Julian Backhouse**

Regulatory Affairs and Labelling  
Consultant,  
Liverpool, GREAT BRITAIN

Owner



**Nina Malvik**

Norwegian Medicines Agency,  
Oslo, NORWAY

Senior Adviser Product Information,  
QRD member, CMDh alternate

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### Day 1 from 09:00 - 17:00

#### Preparation on ePI in pharmaceutical companies

Dr Niklas Jänich

- ePI in a global context
- Challenges for the pharmaceutical industry
- Integration of ePI into the labelling process
- Practical experiences with special consideration of the EMA ePI pilot

#### Insights from the IMI Gravitare-Health project

Dr Giovanna Ferrari

- Introduction to IMI Gravitare-Health
- Overview of key achievements and insights
- The role of an interoperable ePI in wider digital health transformation
- Next steps for Gravitare-Health and future opportunities

#### Labelling supported by artificial intelligence (AI)

Dr Niklas Jänich

- Prerequisites for using AI in labelling
- Leveraging AI for similarity analysis in labelling
- Further practical examples and insights
- Challenges and lessons-learned

#### Next generation labelling

Tris Nockles

- Transformational potential of emerging technologies (AI, digitalisation) on labelling
- Skills and functions needed for digital and AI-driven labelling
- Anticipated changes in the operating model of labelling organisations
- Practical steps and strategies for companies to prepare for the future

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### Day 2 from 09:00 - 12:30

#### Updates from the QRD group and the Norwegian medicines agency

Nina Malvik

- QRD template revision - improvement of package leaflet
- Examples for acceptance of EN only packs in Nordic countries - regulatory flexibility to improve availability of medicines
- Accessibility of digital package leaflet via FMD 2 D bare code

#### To what degree will intelligence and automation, shape the future of labelling?

Julian Backhouse

- The big picture - up- & downstream
- Build or buy label information management?
- Will GenAI remove the need for content based authoring?
- What is a label content factory and why you need one?
- The labelling vendor cloud

## REGISTRATION UNDER

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## REGISTRATION FORM

Yes, I will attend

☐ ExpertFORUM Labelling

☐ 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

23 - 24 October 2024 - online

Day 1: 09:00-17:00; Day 2: 09:00-12:30

You may dial in 30 min before the session.

### Fee

€ 1,590.00 (+ German VAT)

The fee includes high-quality course material for download, a participation certificate, access to the Learning Space as well as technical support including a test meeting.

Name

Position, department

Company

Street

Post code, city, country

Tel. no./Fax no.

E-mail

Contact person at office

Date, signature

### How our online events work

- Our online events are live and interactive. They can be accessed in the Learning Space, where you will also find the programme, the list of participants and all relevant documents.
- You can access the Learning Space with the same account you use for the customer portal.
- The free pre-meeting helps you resolve any technical issues before the event.
- Continuous support during the online event guarantees that you concentrate entirely on the training.

## CANCELLATION POLICY

Our general terms and conditions (as of 01 June 2024) apply and are available upon request. We can send them to you at any time. Alternatively, you can access them online at [www.forum-institut.com/t&c](http://www.forum-institut.com/t&c)

## YOUR CONTACT



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