

# Meet with ZWIERS!

## 2dayRA 3&4 November

- **Two days** course
- **Essentials** and more
- **Comprehensive** and interactive



### PROGRAM DAY 1

#### **RA: all through drug development**

Refresher drug development and RA involvement

#### **Dossier: content in a common format**

Electronic Common Technical Document

#### **Lunch**

#### **Procedures: obligations or opportunities?**

EU marketing authorisations applications and the US New Drug Application

#### **DIY!**

Cases and assignments to work with the dossier and procedures

### PROGRAM DAY 2

#### **What's new?**

Quiz on COVID19 illustrating regulatory tools

#### **What's next?**

Post approval regulatory requirements and activities

#### **Lunch**

#### **Pharmacovigilance: detect, assess, understand and prevent.**

Explanation on the science and activities related to adverse events

#### **Pave the path: regulatory strategy**

Interactive session on legal basis, abridged dossiers, exclusivity, special products/procedures

**3&4 November 2022**  
**Oss offices**  
**€750,- fee**  
**Lunch included**