Meet with ZWIERS!

2dayRA

- **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

Oss offices
€750,- fee
Lunch included

ZWIERS
Regulatory Consultancy