Sneak Peek

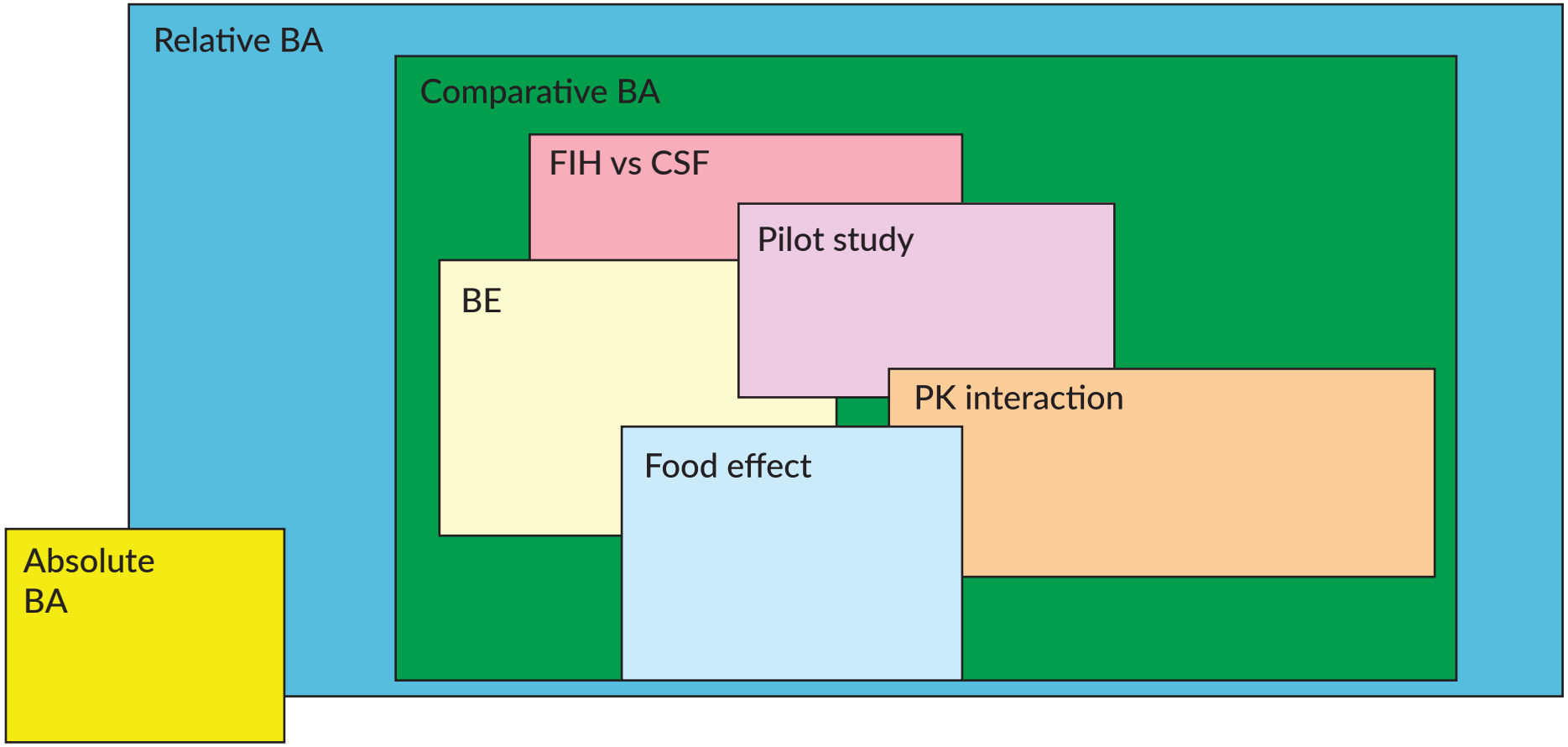
Bioequivalence and IVIVC

Dr. Paula Muniz
Dynakin,
Senior Associate

ONLINE
TRAINING

Overview of relative BA/PK study types

01



Bioequivalence: with what?

- Parent compound is considered to reflect better absorption rates
  - Also in cases where parent compound is a prodrug and activity is driven by metabolites
  - If prodrug cannot be reliably measures, BE may be based on first metabolite

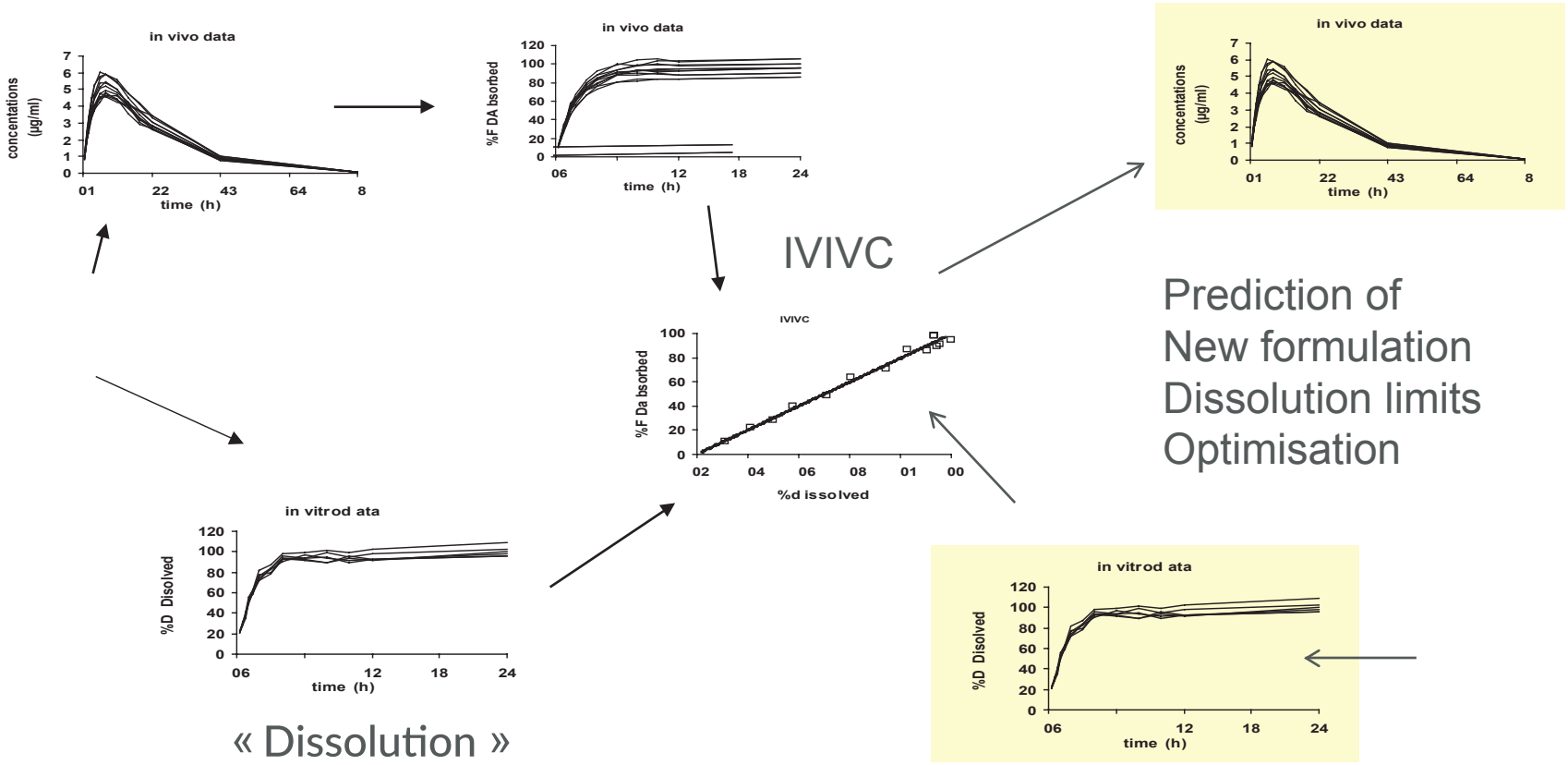
- ***"In rare cases, parent drug and primary active metabolite should be considered, e.g., drugs that have metabolites formed through gut wall or gut lumen metabolism that contribute to efficacy or safety"*** **(ICH M13)**

Bioequivalence testing

- Alpha considers the type I error (falsely concluding bioequivalence): patient risk
  - Defined as 5%
- Power considers the type II error (falsely NOT concluding bioequivalence): sponsor risk
  - Usually target 80-90%
- Point estimate of the Geometric Least Square Means ratio between T/R, 90 % confidence interval that the true ratio is between lower an upper margin
  - 100-2*alpha
  - Sequence and period are factors in the ANOVA
  - Ratio depends on product differences
  - Breadth of 90% CI depends on variability/sample size
    - Critical to define sample size

IVIVC in theory

« Absorption »



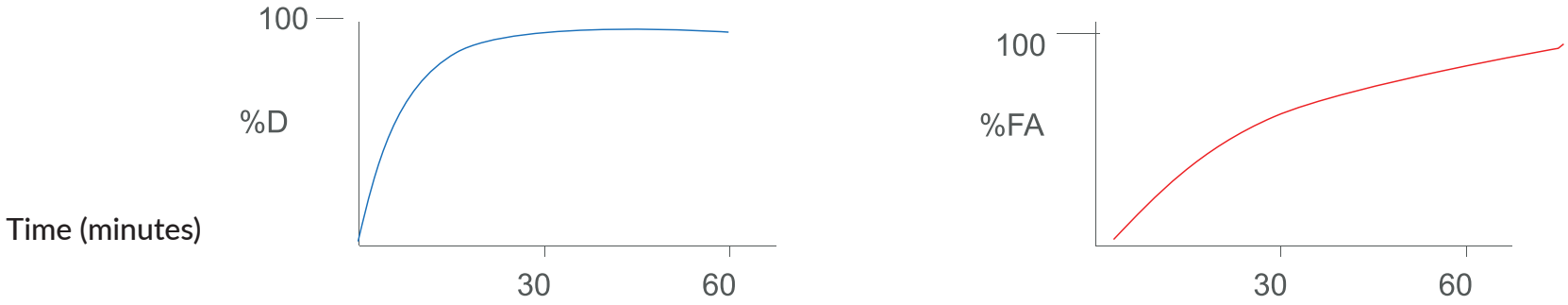
Prediction of
New formulation
Dissolution limits
Optimisation

« Dissolution »

If a correlation between *in vivo* and *in vitro* behavior can be established then new batches or similar formulation behavior can be predicted and *in vivo* relevant dissolution limits can be defined

Time scaling

- Why?
  - Dissolution test time in minutes/hours
  - In vivo times longer hours, even days



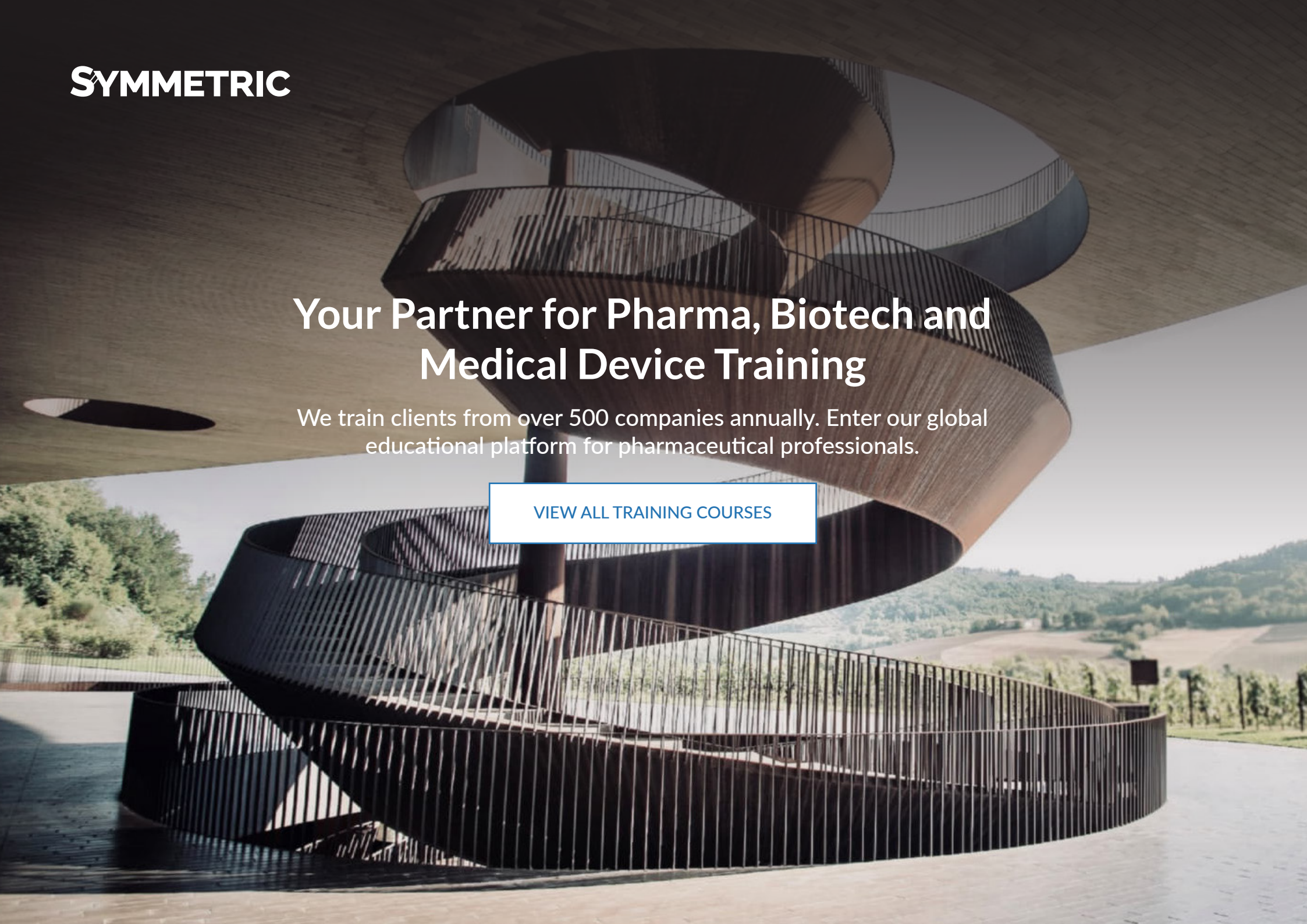
- How does it help?
  - Apply a correction for the time difference
  - Allows correlation even if *in vitro* rate is faster than *in vivo* rate
  - Allows to explore if all formulations share the same relationship
    - If not but can establish for test products, could estimate the *in vitro* profile of the test product based on the *in vivo* profile of the reference
    - CANNOT include a formulation with a different time scale in the IVIVC

Registration

Sneak Peek

Bioequivalence and IVIVC

Mliekarenská 9, 821 09
Bratislava, Slovak Republic
ID: 47 068 124
VAT no: SK2023741973
Office: +421 948 262 346


SYMMETRIC
Your Partner for Pharma, Biotech and Medical Device Training
We train clients from over 500 companies annually. Enter our global educational platform for pharmaceutical professionals.
VIEW ALL TRAINING COURSES