ADaM to ‘A-ha!’: When a Clinical Data Scientist Interprets the Results

Challenging traditional roles by moving from ADaM and TFL development to result interpretation in clinical trials.

Carlotta Porcelli, Clinical Data Science Specialist

cxpo@novonordisk.com

Phuse SDE Copenhagen
22 Oct 2026

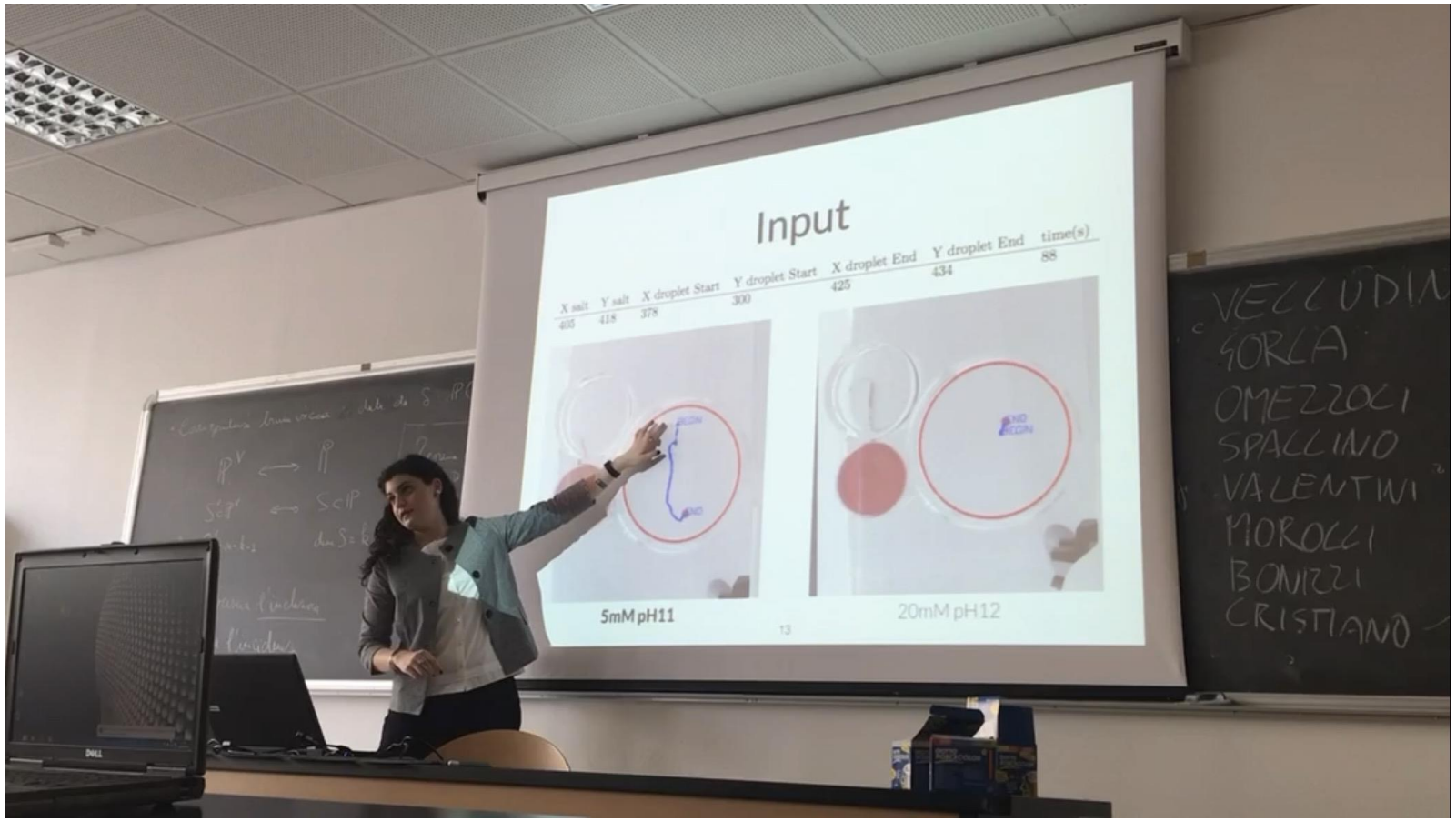
Disclaimer



Views and opinions expressed are those of the speaker and not necessarily Novo

A-ha - Wikipedia

2012


Input
X salt
405
Y salt
418
X droplet Start
378
Y droplet Start
300
X droplet End
425
Y droplet End
434
time(s)
88
5mM pH11
20mM pH12
13
VECCHIA
GORLA
OMEZZOLI
SPALLINO
VALENTINI
MOROLLI
BONIZZI
CRISTIANO

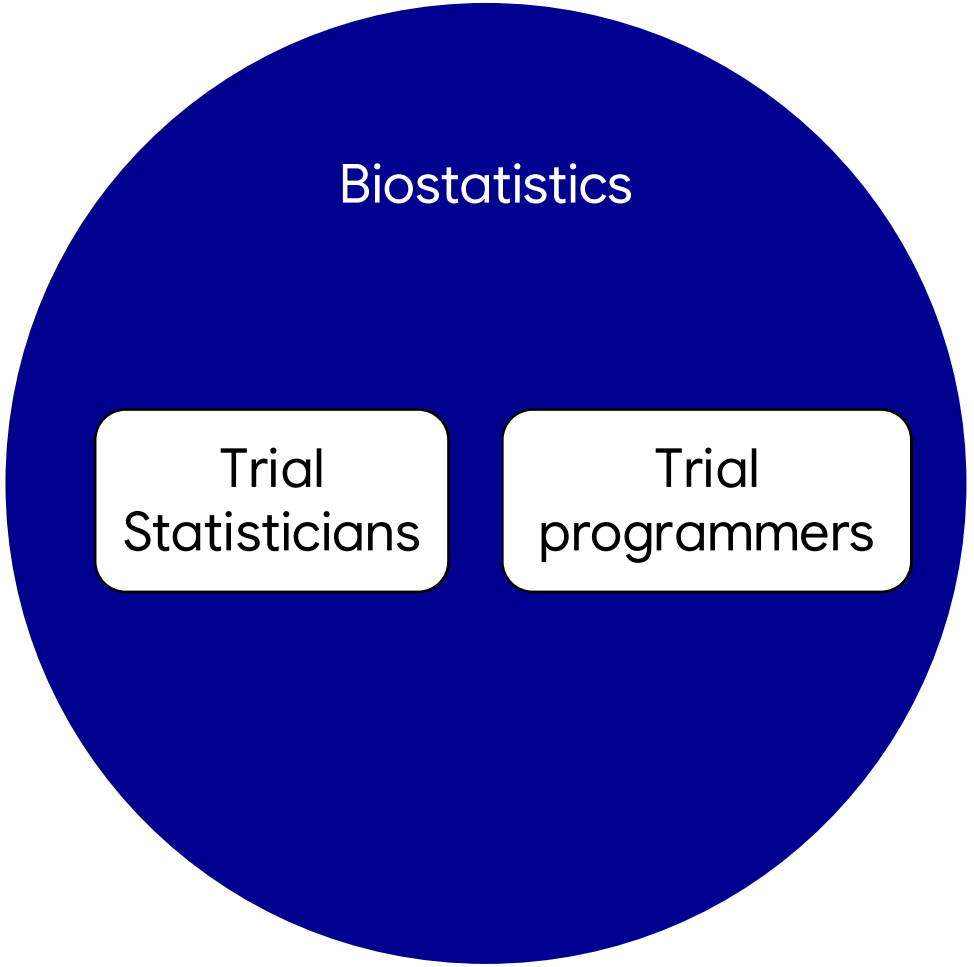
2018


Mass spectrometry data analysis
and visualisation of the IL-17A osteoarthritis study
Carlotta Porcelli, MSc Bioinformatics
Internal supervisor: Albin Sandelin
External supervisor: Anne-Christine Bay-Jensen
1st October 2018
UNIVERSITY OF COPENHAGEN
NORDIC BIOSCIENCE

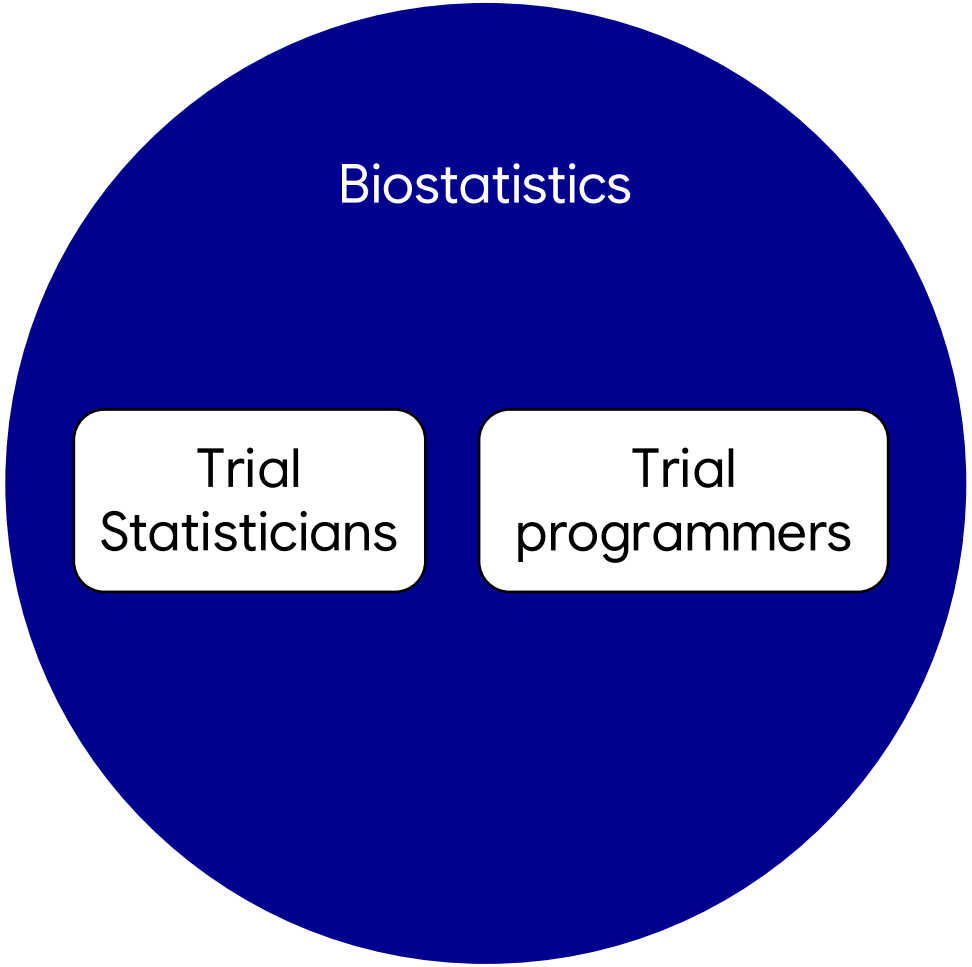
2023

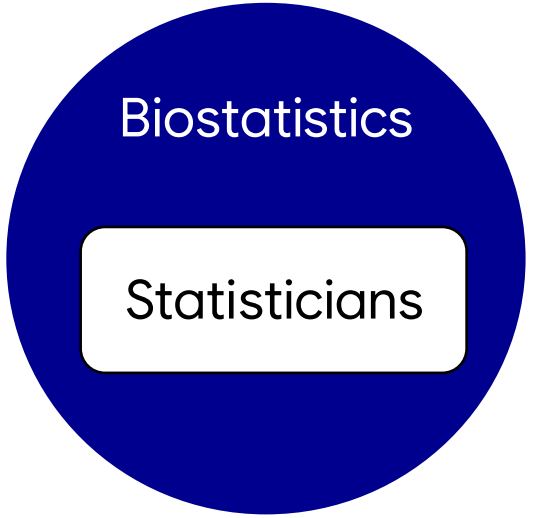

UNIVERSITY OF COPENHAGEN
Functions of m6A-YTH modules in plants
Lessons from high-throughput sequencing analyses
Carlotta Porcelli
11th August 2023

- until 2025



present







Statistical programmers -> Clinical Data Scientists

From last year's presentation

Vision

"By September 2026, we (the CDS) will be widely acknowledged as a leading innovative partner, known for data-driven, scientific and operational insights to accelerate product development and maximise impact"

Anna Berglind, Mindset Matters, Phuse SDE Copenhagen 2025

Purpose

Enable decision-making

Anna Berglind, Mindset Matters, Phuse SDE Copenhagen 2025

Yes, but how ?

Responsibility split of Biostatistics and CDS for *Trial activities*

ACTIVITY	Biostatistics	CDS	Notes
COMMUNICATION			
Interpretation of results, correctness of applied methods, **communication of results**	Responsible Accountable	Consulted Informed	For trials with no / standard statistical analyses, the responsibility can be reversed – based on evaluation of PLF

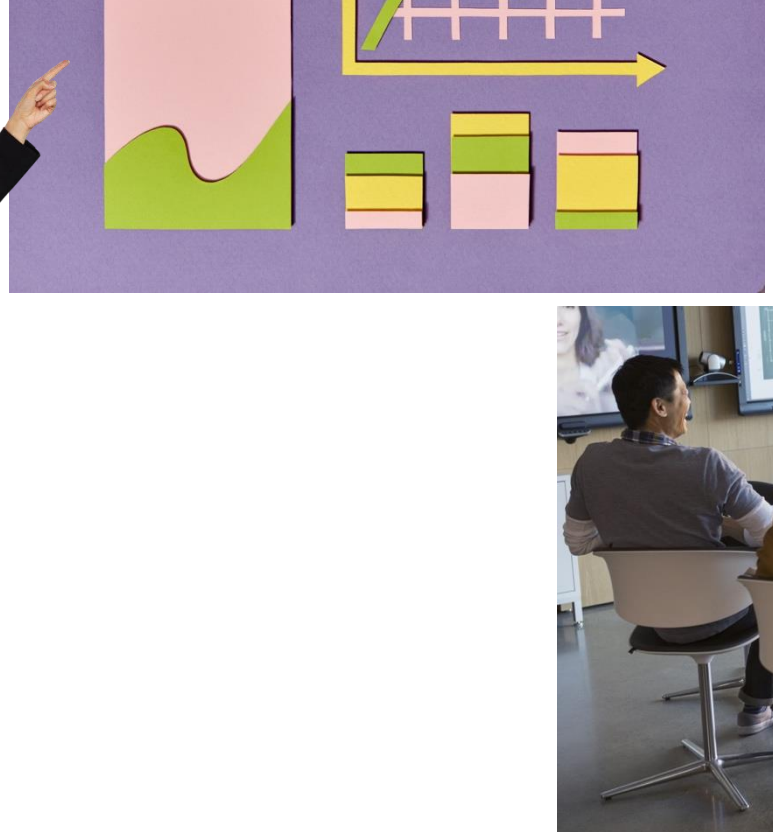
PLF: Project Leadership Forum – senior directors from biostatistics and CDMP

Responsibility split of Biostatistics and CDS for *Trial activities*

ACTIVITY	Biostatistics	CDS	Notes
COMMUNICATION			
Interpretation of results, correctness of applied methods, **communication of results**	Responsible Accountable	Consulted Informed	For trials with no / standard statistical analyses, **the responsibility can be reversed** – based on evaluation of PLF

PLF: Project Leadership Forum – senior directors from biostatistics and Clinical Data Management and Programming

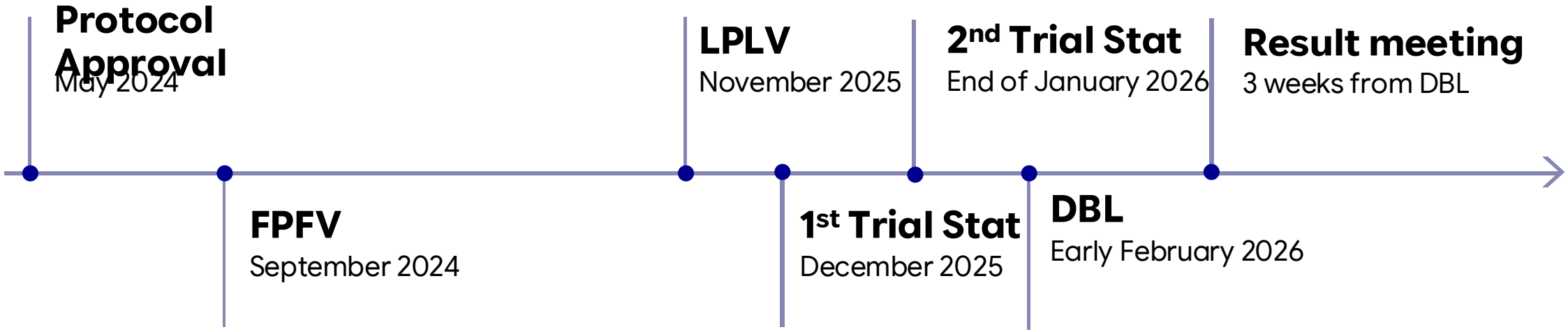
2026





How did I end up there?

Study events & resources



Lead CDS

Trial CDS

Trial Stat

Trial Stat

Project Stat & Project CDS

The study

- Phase 1 trial: safety and tolerability of the IMP
- SAD and MAD cohorts
- Primary endpoint: the number of treatment emergent adverse events
  - Changes in safety parameters from baseline to end of study
  - Occurrence of anti-drug-antibodies
- Secondary endpoint: to investigate the pharmacokinetics and pharmacodynamics of the IMP
  - C_{max}, $AUC_{0\text{-}inf}$ / $AUC_{0\text{-}24h}$
  - Changes in pharmacodynamics parameters from baseline to end of study

Standard statistical analysis 

IMP: Investigational Medicinal Product; SAD/MAD: single and multiple ascending dose; C_{max}: maximum concentration of IMP after doses; $AUC_{0\text{-}inf}$: Area Under the Curve from 0 to infinite

The decision

- Onboarding a new team member
- Get to know the study, the data, the analysis and the results
- Organise the meeting(s)
- Align stakeholders (never met before)
- Prepare results slides
- Organise the review process
- Communicate the results

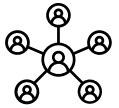


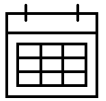
Let the Trial CDS lead all activities

Endorsed by the PLF

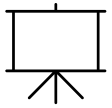
How did I do it?

1. Not alone !
2. Created a thorough plan to map all activities in the short period of time
   - Read through the SOP and the guidance on the process
   - Sent out meeting invites to the stakeholders (supported by PStat & Global Project Leader)
   - Aligned supporting CDSs on the timelines, and had (short) weekly update meetings
3. Preparation of content*
   - Proposed an initial draft by selecting outputs supporting the endpoints
   - Aligned with the statisticians on the content, the story and the interpretation
   - Aligned the initial draft with the rest of the stakeholders









** Led to the development of an automated template program to build slides in Quarto, with outputs embedded directly from the study output catalogue*

Be the leading partner

- **Connect** with the Clinical Pharmacology & PK Modelling specialists
  - are there any patterns in the PK profiles that we should focus on?
  - is the IMP "behaving" as we expected?
  - is the terminal phase selection accurate?
- **Connect** with the Safety Surveillance & Medical specialists
  - *why* are *these* laboratory parameters (safety and pharmacodynamic) important for the study?
  - *what* do we (expect to) see from the data? And what *does it mean* for the participants?
    - do we see a *dose dependent* response in these parameters?
  - are there any concerns for *this participant* having *such a levels of XYZ?*
- **Connect** with Immunogenicity specialist
  - is there anything *concerning* in the results of the anti-drug-antibodies?

PK/PD review process

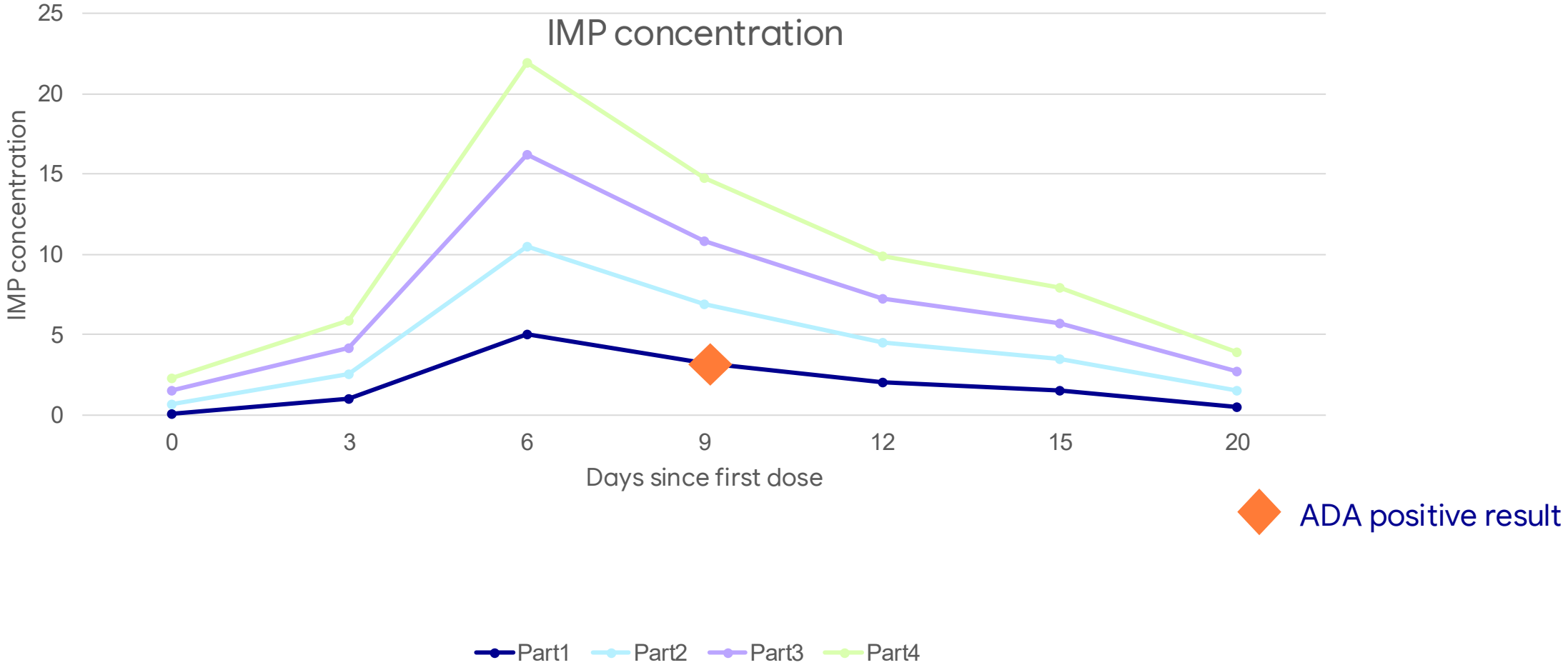
Accelerate product development

The IMP is considered safe and well-tolerated

The results of the study support continuing the clinical development of the IMP

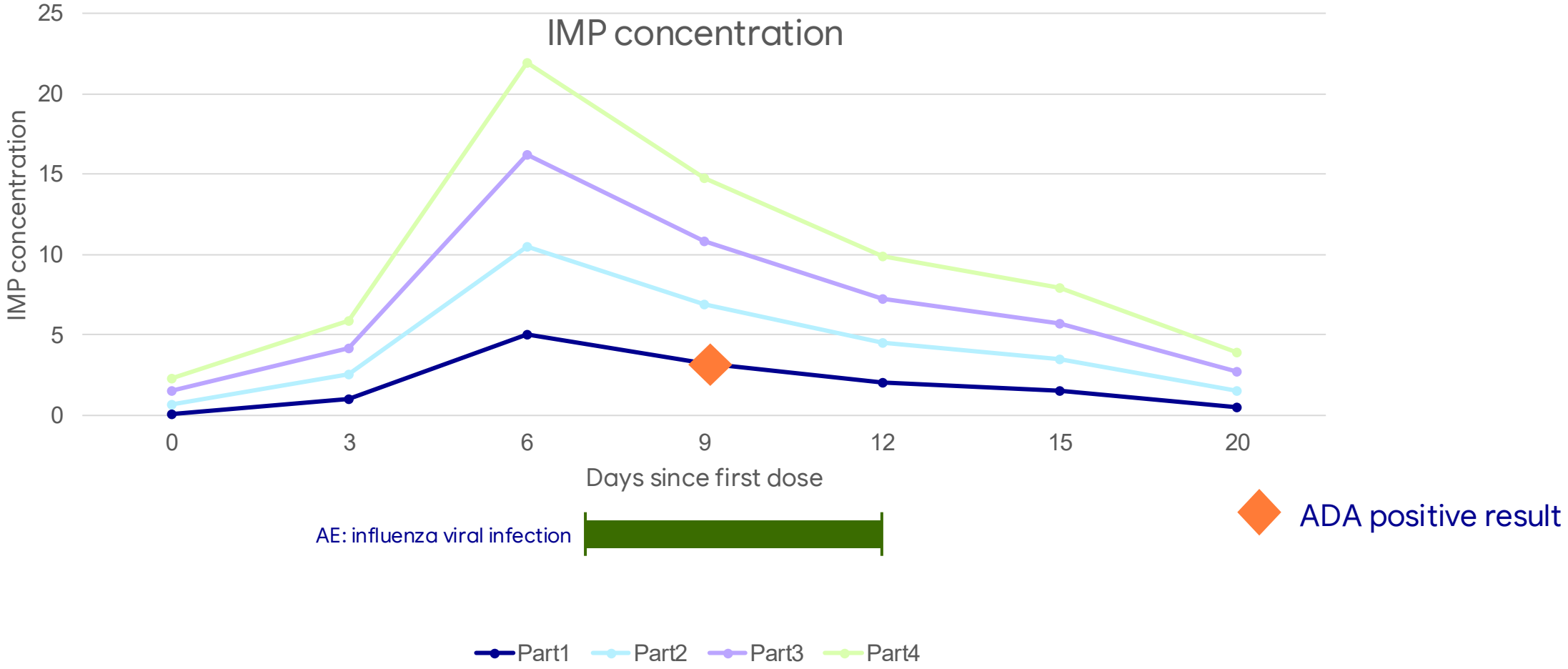
IMP: Investigational Medicinal Product

Enable decision-making, by being data-driven



IMP: Investigational Medicinal Product; ADA: anti-drug-antibody

Enable decision-making, by being data-driven



The positive ADA result is not clinically significant

IMP: Investigational Medicinal Product; ADA: anti-drug-antibody

Enable decision-making, by being data-driven

Most AEs: nasopharyngitis

Recording of AEs

October January

From public data



From ADaM to A-ha!

An **aha moment** is a sudden flash of insight or comprehension when a complex problem, missing piece of information, or abstract concept suddenly becomes clear and obvious



Eureka effect - Wikipedia

Questions?