

Working with Pharma and CROs

An ARO perspective

Aize Smink, CEO Julius Clinical
February 6th, 2020



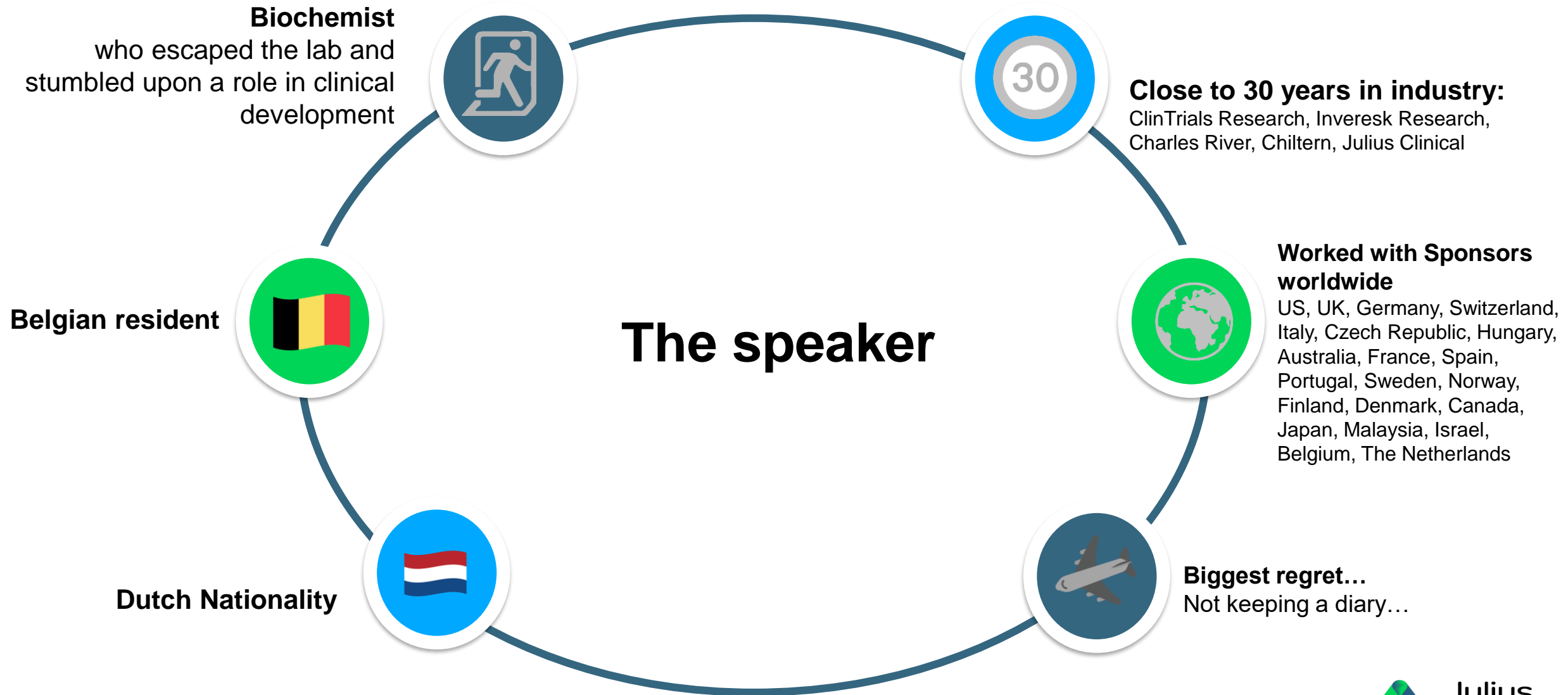
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Disclaimer

Like many types of organisations the ARO landscape is varied:
Commercial / not for profit, small and large etc.

Objective

Create a better understanding of the ARO sector
Difference between CROs and AROs



Snapshot of Julius Clinical



Corporate profile

Founded in  **2008**
and affiliated with the
University Medical Center Utrecht

Corporate office in
ZEIST,
The Netherlands



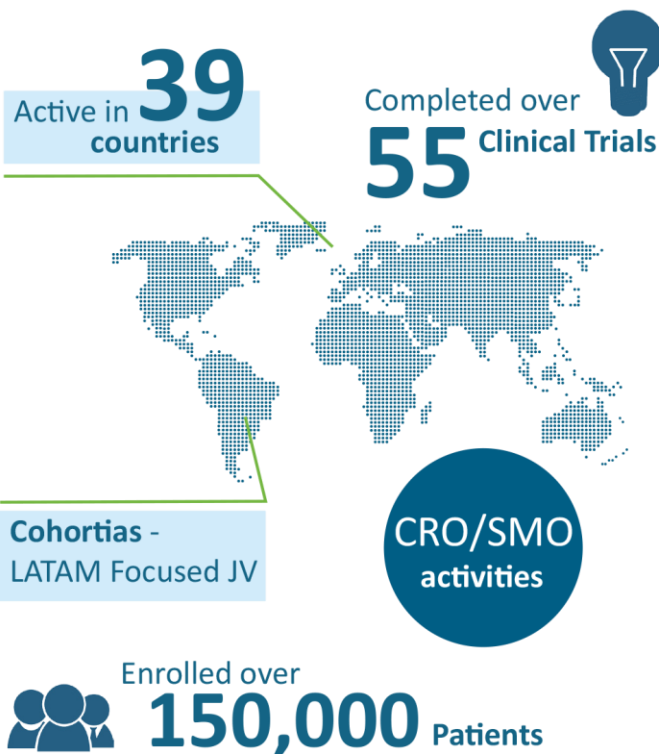
140
employees



Partnering with **experts** in
Europe, the Americas and Asia



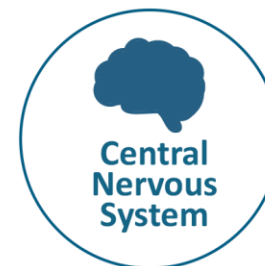
Global reach



Expertise



Infectious Diseases
& Immunology



Central
Nervous
System



Cardiovascular,
NASH, Metabolic
and Renal disorder

Trial Innovation
and Real World
Evidence



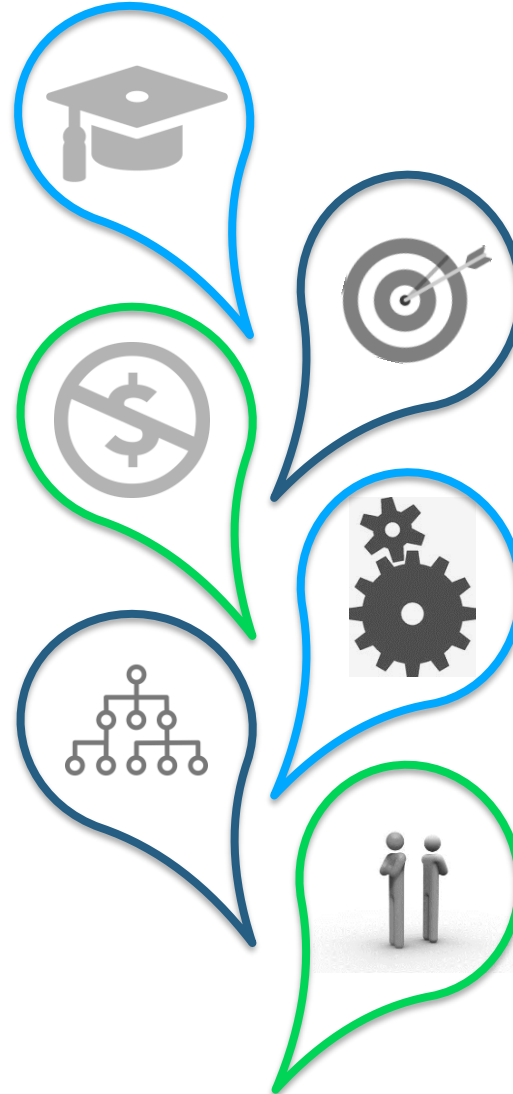
Investigator
Initiated Trials

ARO specifics

Academic background / environment

Many AROs do not have a purely commercial focus

Selection of staff is more focused on scientific merits



For most clinical researchers in an academic environment clinical trials are not their core business

Traditional motivators may therefore not work, however other aspects are important

- Do my patients benefit
- Does my reputation benefit
- Can I publish
- Is my organisation benefitting

Some of these may create conflicts with Pharma

ARO Costs and Contracts

- > Costing model does, not surprisingly, usually come from Academia
 - > Based on labor costs with overhead
 - > Generally academia are overhead heavy.. Most AROs reflect this in their pricing
 - > The concept of value is perhaps different between a Scientist and the industry
 - > On the otherhand, scientists are less burdened by standards and more willing to think out of the box.

- > Contracting
 - > In many cases contracting is performed by external staff, not necessarily under direct control of the ARO.
 - > Not always extensive experience with the clinical trial context
 - > Climate generally risk averse.. not unlike Pharma
 - > Challenges to commit to some terms imposed by Pharma

Pharma

An ARO view

> Business culture vs scientific culture

- Worlds apart?
- Reputation of Pharma
- Working with pharma is all about contracts
- Lag between discussion and decision
- Investments required within Academia
- Progress reporting

> Process focused, deviations not always easy

- Scientists like to think outside the box..
- Admin burden
- Training of staff
- Use of systems
- Focus on the result

CROs vs AROs

CROs

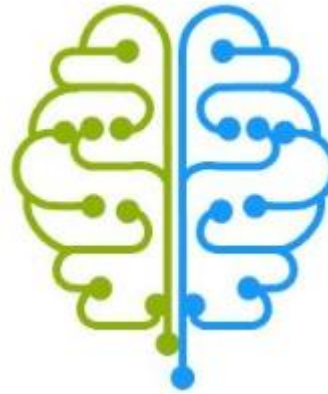
Most CROs are tightly managed efficient global delivery organisations

Budget and profit focused

Mostly process focused – tickbox mentality

More client than site focused

Centralised innovation with a business focus



AROs

Most AROs are science and network focused

Collaboration with scientific peers

Can lead to higher motivation of sites

Client focus does not always come natural

Focused on Scientific innovation

Similarities?

Pharma

- Mature
- Global
- Challenges with Innovation
- Marketing & sales

CRO

- Large CROs have started behaving more like pharma

Biotech

- Start up / Entrepreneurial
- Local
- Science as innovator
- R&D Focus

ARO

- AROs in terms of approach to science and innovation act more like Biotech

It is all about collaboration

1

Respect the potential cultural differences

What is the motivation to participate in this study

2

Be flexible where you can.

- Contract terms
- Other requirements

3

Scrutinize the team assigned and make sure your expectations are clear

- Credentials, time allocated etc
- Confirm scope, especially when more parties involved



Confirm reporting framework, timelines etc.

- Formal reporting requirements
 - Meetings / attendees

4

Establish governance

5

Thank you



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