Ad Hoc Clinical

Willing, eager and able

to carry out your clinical trials

ad hoc CLINICAL

Key Facts

- Founded in 2009 by Nancy Cottigny
- Start-up and monitoring services
- Headquartered in Ypers, Belgium
- Privately owned company
- 11 permanent staff (FTE)
  - 9 in Belgium
  - 2 in France
- Large network of similar organizatons/colleagues all over Europe

Who's your typical Client?

1) Small biotec or pharma

2) CRO 's

3) Investigators

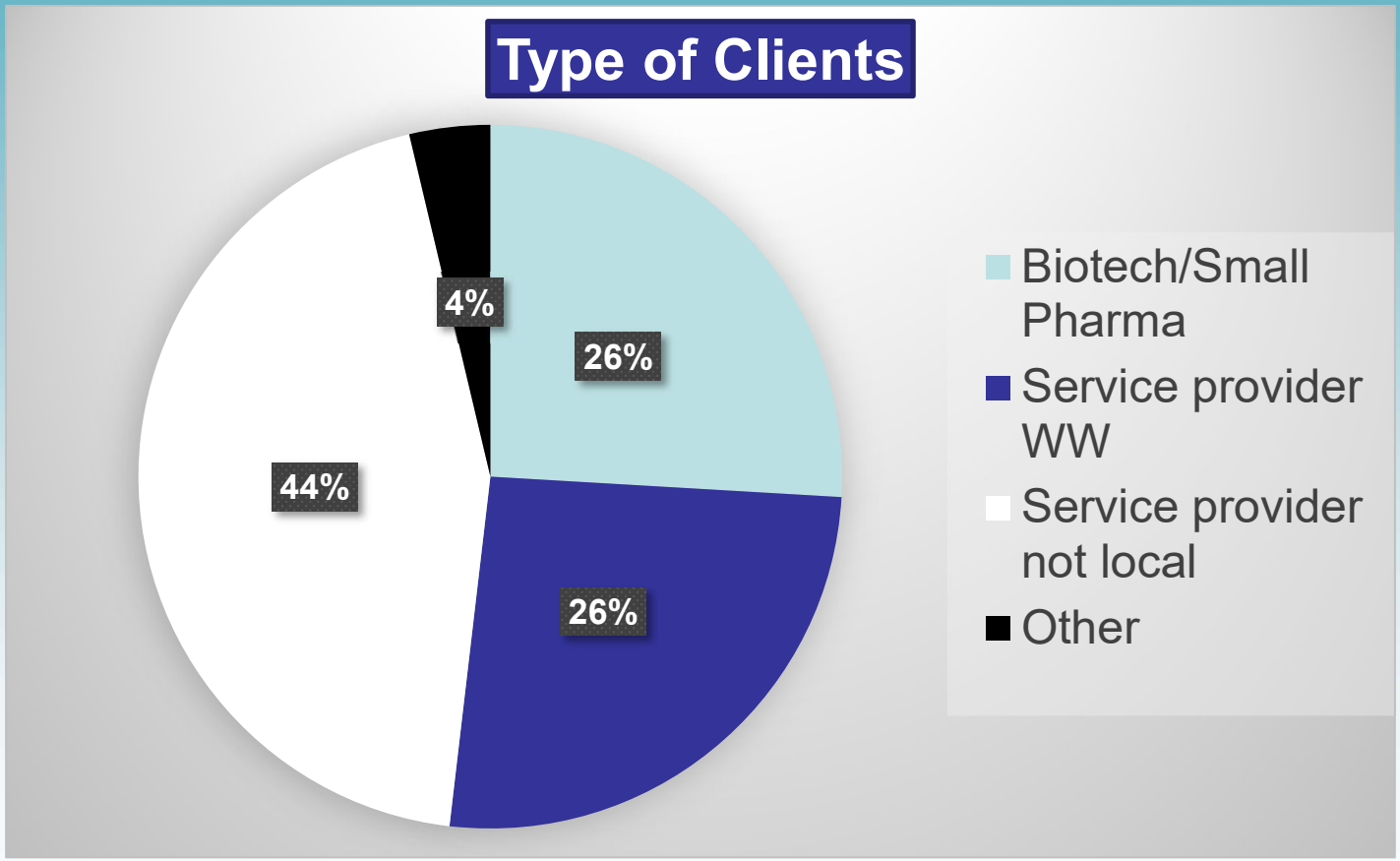
4) Other service providors

Who's your typical Client?

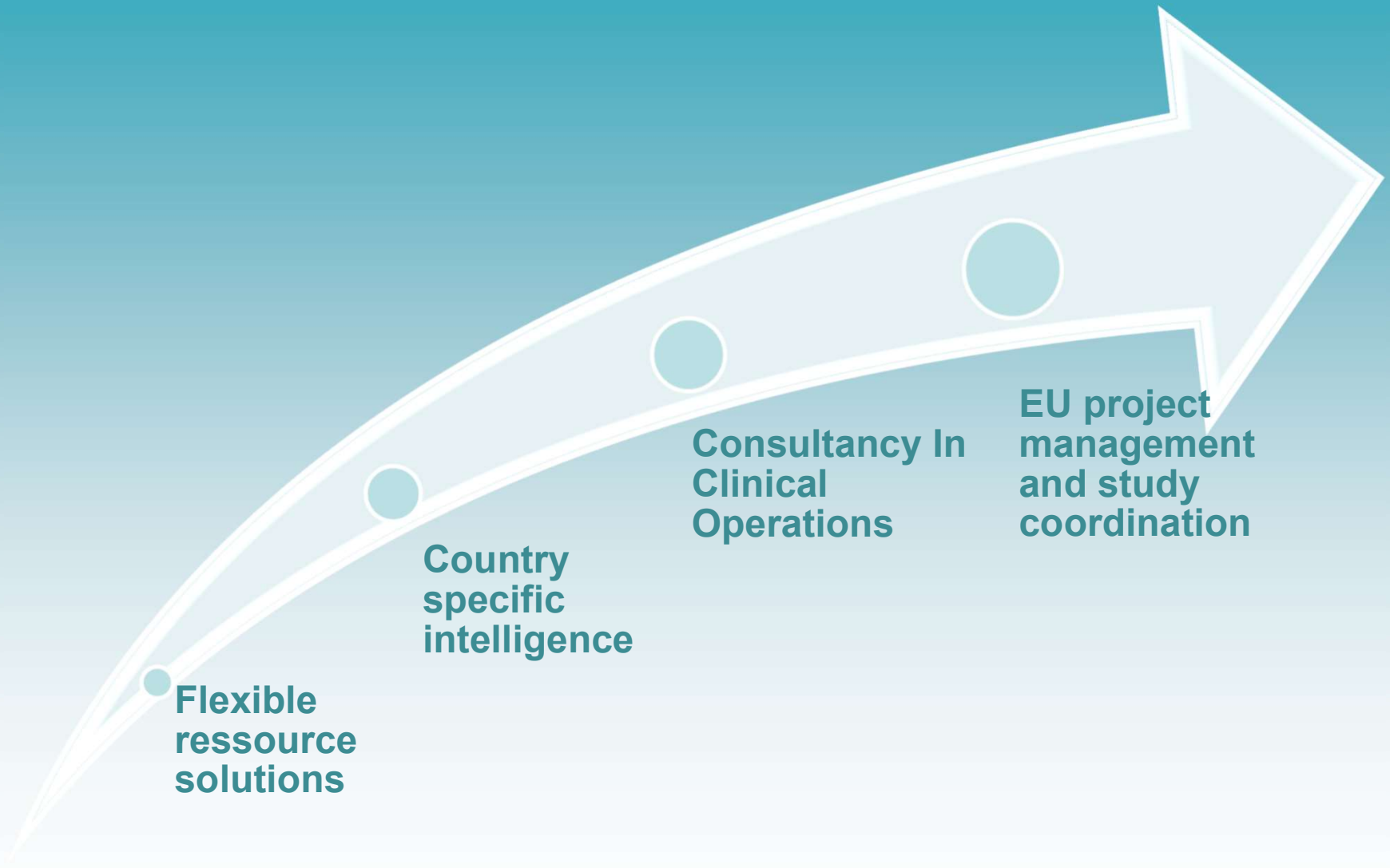
- Large CROs
- Pharmaceutical industry
- Medical device companies
- Biotech industry
- In vitro diagnostic industry

45 clients over the last 10 years
(88 % repeat business)

Who's your typical client?



What do they need?



What do they ask for?

- Find me interested / interesting investigators
- Prepare regulatory submissions in a specific country
- Arrange for investigator / hospital contracts
- Provide me with adequate SOPs and study documents
- Coordinate Clinical Operations activities over multiple countries
- Organise site management and monitoring
- Train my staff
- Provide me with temporary ressources

What services do you provide?

Functional sourcing

- Fully trained, GCP certified **staff is contracted** to our clients.
- Client sources the **required expertise** (e.g. study start up specialist, junior CRA, senior CRA, Project Manager, Auditor).
- Allocated staff is either home based or works from our offices in Ypres (Belgium).
- Client makes an estimate of the required workload, we plan accordingly.
- Resources (either freelancers or permanent staff) selected for you **anywhere in the EU**
- A back up can be organized internally if required/accepted by client.
- We work **with your SOP's and report to either your PM or** the PM of your client.
- Day to day supervision organized by Ad Hoc Clinical as an optional service.

What services do you provide?

Project services

- An **entire study** or **selected tasks** are entrusted to Ad Hoc Clinical (e.g. submissions to EC/CA, site contract negotiations, monitoring, overall study coordination).
- All activities are executed per **Ad Hoc Clinical SOP's,** training to SOP's is included in the service.
- **Project is managed**, organized and supervised by **Ad Hoc Clinical Project Managers.**

What tasks can I delegate?

- Clinical Trial set up and Project Management
- Development of study documents
- Site selection
- Feasibility studies
- Customizing Informed Consent forms to country specific needs
- Obtain advice from EU Ethics and Competent Authorities
- Site contract negotiations
- Study initiation visits
- On site data abstraction (on site CRF completion)

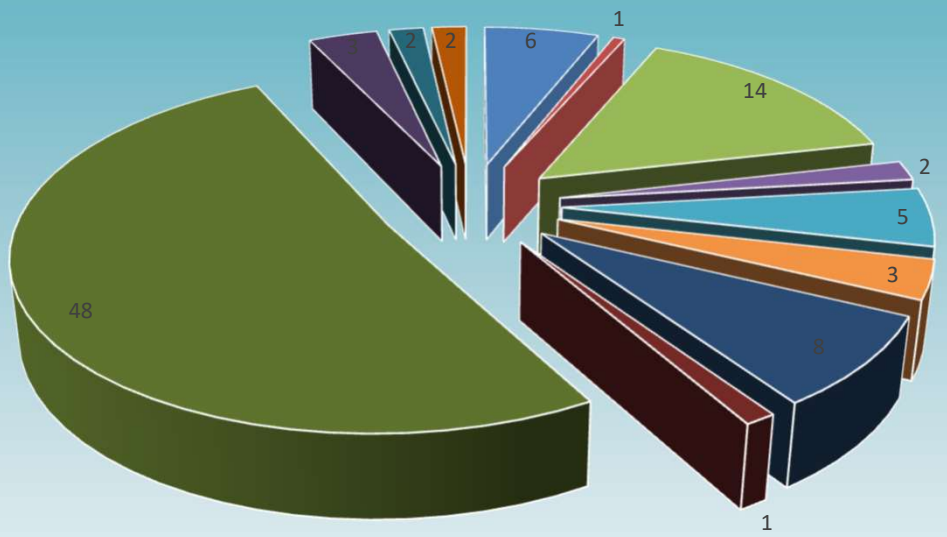
Services continued…

- Remote and/or on site monitoring
- Site management
- Clinical Project Management
- Third party selection (e.g. data management service provider, central laboratory...)
- Training and coaching of CRA's
- SOP writing
- Consultancy
- Auditing
- Advice / inform and train you on the GDPR (EU data protection regulation)

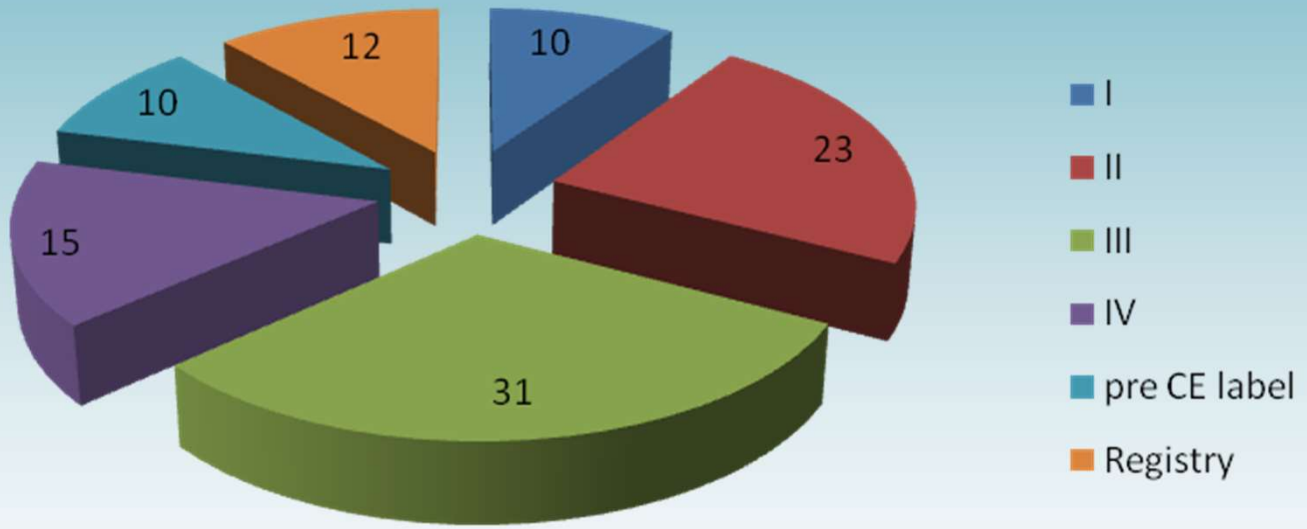
Key Factors of Success

- Multi-disciplinary teams
- Local Country experts everywhere in the EU
- In depth knowledge of local / EU regulations in the field of clinical research
- International experience / network
- Personal approach
- Direct communication lines
- Flexibility and “can do” attitude
- Straightforward processes and procedures
- Expertise and supervision of senior management

Therapeutic experience



Study experience



What is your geographical coverage?

Blue country :

France – Belgium – The Netherlands:

Covered by Adhoc Clinical internal teams

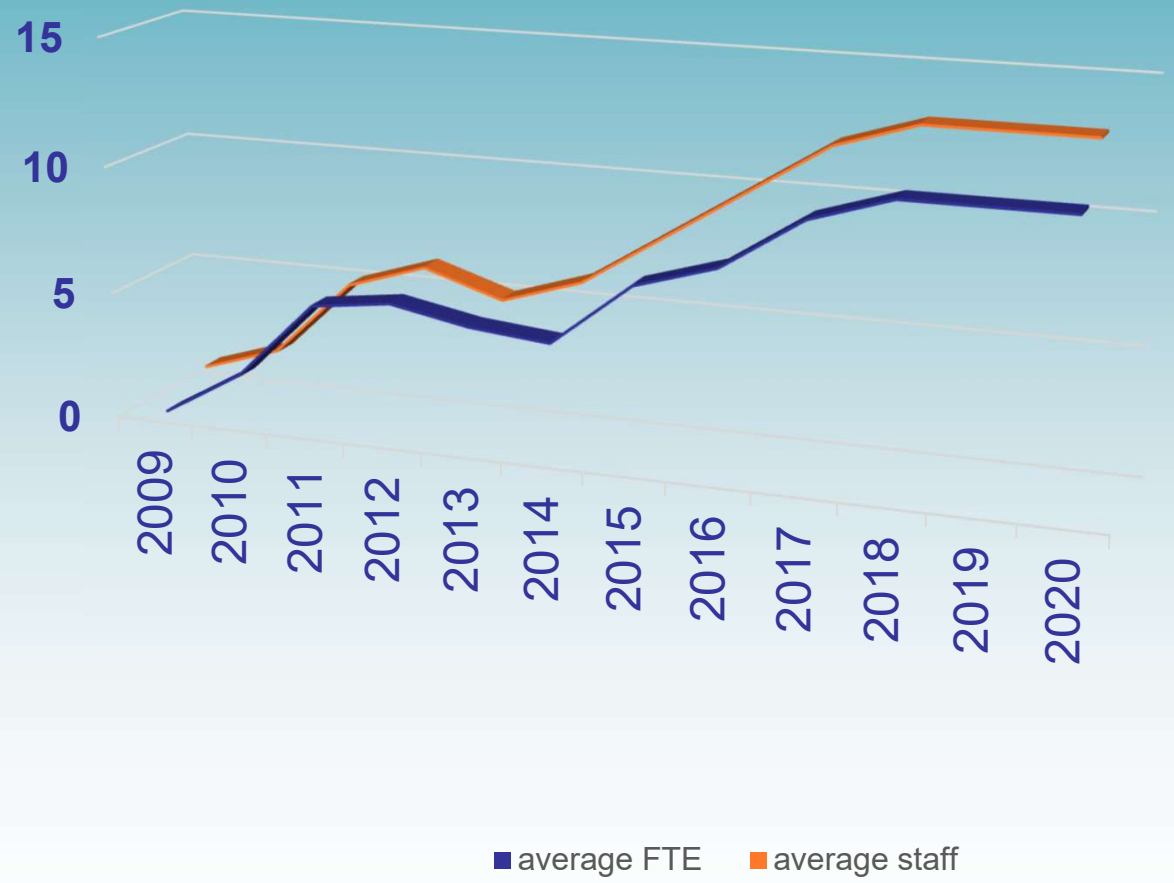
Orange country :

Covered via third party service providers

15

Facts and figures

Growth in permanent team



Case study 1

Regulatory services

Clients need:
A client is involved in late phase research and has various EU projects in the pipeline with different regulatory pathways.

Services rendered:

- Investigate per project the country specific regulatory pathway.
- Report to client what the Regulation is in the EU overall + local country specific requirements.
- Proactively identify potential pitfalls allowing client to set up a regulatory strategy per country.
- Do the required EC and CA submissions and FU untill advice is issued.
- Provide EU staff to client (functional sourcing).

Case study 2

Readily available ressources for local clients

Clients need:

A large local CRO is short in staff to execute projects they have been granted. They need local experts to inmediately hit the ground running and start the activities untill their internal ressources have the required capacity.

Services rendered:

- Prepare country specific study documents.
- Prepare EC submissions in name of the large CRO.
- Facilitate site contract negotiations.
- Perform onsite site qualifications in name of large CRO.
- Perform onsite and remote monitoring visits in name of large CRO.

Case study 3

EU Project coordination

Clients need:
An US Biotech is organising internally the set up and project management of a phase III clinical trial including US sites and various EU countries. This is the first time they are active in the EU and asked Ad Hoc to provide “oversight”.

Services rendered:

- Adapt client SOP’s to be fit for EU activities.
- Assist in streamlining the EU regulatory submissions.
- Select and provide oversight to freelance CRAs in various EU countries.
- Participate to client board meetings and communicate pro actively on EU requirements / issues affecting clients objectives.

Case study 4

Act as an EU extension of a US based CRO

Clients need:

An US based CRO has no (fix) teams in Europe and has been entrusted with a large study with both US sites as EU sites. They need local experts to immediately hit the ground running and start the activities ensuring a streamlined approach and delivering the same quality of services in the EU as in the US.

Services rendered:

- Prepare country specific study documents.
- Act as a regulatory specialist for Europe.
- Prepare regulatory submissions for the large CRO.
- Facilitate site contract negotiations.
- Do onsite site qualifications in name of large CRO.
- Do onsite site monitoring visits in name of large CRO.

Case study 5

Auditing

Clients need:
A Biotech company is getting ready to submit for a Marketing Authorisation for one of their lead compounds. The research has been done by a CRO but the client wants an independent auditor to check the files prior to submitting for MA .

Services rendered:

- Discuss with management where the potential issues lay.
- Do an overall check of study documentation.
- Identify and cathegorised all issues encountered.
- Reconciliation of Trial Master Files.
- Summary of Gaps from the reconciliation.
- Closing of Gaps identified.
- Coaching in Clinical trials management (train and review SOPs).

Could you use some help?

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