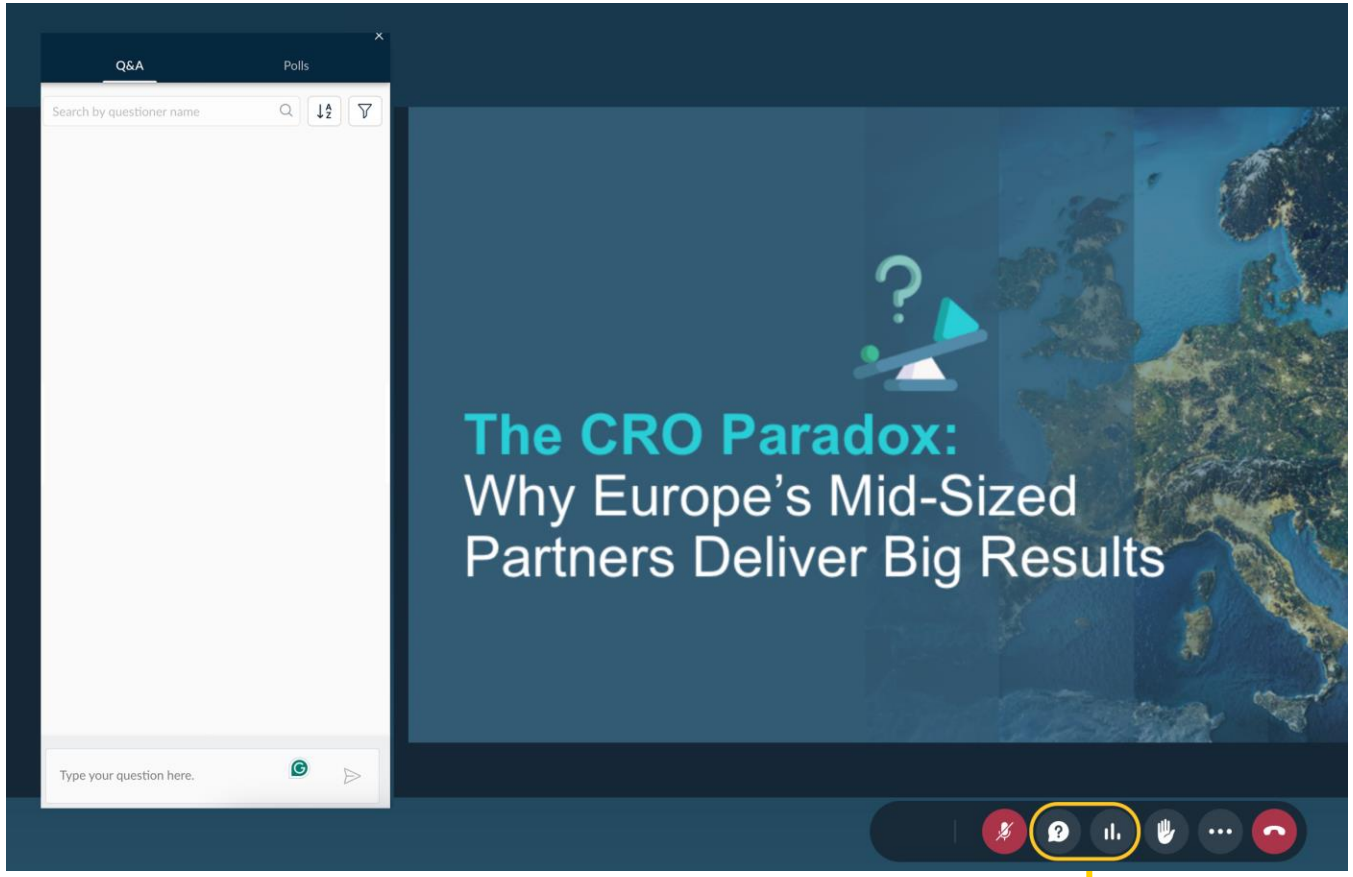
The CRO Paradox:
Why Europe’s Mid-Sized Partners Deliver Big Results

Agenda

TOPIC	TIME (CUMULATIVE)	PRESENTER
Welcome & Opening Remarks	5 min	Christian
Spotlight on Western Europe: Why This Region?	15 min	Tanja
Spotlight on CEE: Why This Region?	15 min	Peter
How Medium-Sized CROs Deliver Tailored Solutions	15 min	Christian
Q&A Session	5 min	Christian
Conclusion & Next Steps	5 min	Christian

How You Can Engage With Us Today

- **Q&A Tab:** Got a question? Drop it in the Q&A tab at any time. We'll take as many as we can live.
- **Live Polls:** We'll launch a quick poll during the session. Please share your honest opinion, it will only take a second.
- **Recording:** Don't worry about taking notes. This webinar is being recorded, and we'll send the replay to you afterward.



Use these buttons to open the Q&A and Poll tabs

Meet the Speakers

Tanja Ouimet

Business & Strategy Director
ILIFE Consulting

A specialist in forging innovative collaborations between CROs, biotech, and pharma. Tanja brings a forward-looking perspective on how partnerships can accelerate development and enhance trial performance.

Peter Windisch

Chief Operations Officer
Comac Medical

With nearly 30 years in clinical research, Peter specializes in operational excellence and trial management. His focus is on delivering innovation, efficiency, and improved trial outcomes across complex international studies.

Christian Buhlmann

Chief Commercial Officer
Comac Medical

A global commercial leader with expertise in business development, marketing strategy, and client relations. Christian has a proven record of driving growth and building international partnerships across Europe, Asia, and North America.

Opening Remarks

Why Size Can Be Both a Blessing and a Hindrance?

- ✓ CROs have outgrown many biopharma companies in scale
- ✓ Large global CROs bring immense resources and expertise
- ✓ Yet sponsors often raise a consistent set of concerns
- ✓ Perceived loss of control and lack of flexibility
- ✓ Communication challenges caused by siloed structures in global organizations

Frequently Voiced Concerns:

- ✓ Slow study start-up and poor recruitment forecasting
- ✓ Ineffective communication and lack of transparency: getting a straight answer can be difficult
- ✓ The “Black Box” problem: limited visibility on a multi-million investment
- ✓ Questionable ROI: paying for brand and infrastructure, but receiving slower, less flexible service with limited senior-level access
- ✓ One-size-fits-all model: standardized processes for efficiency at scale, but limiting agility and customization

Consultant's Role

Increasingly Critical & Sophisticated

- ✓ Act as strategic partners, navigators, educators, and amplifiers for sponsors
- ✓ Provide clarity and guidance in navigating the complex challenges often associated with large CROs
- ✓ Three key phases: Strategic, Execution, and Oversight

Focus on Strategic Phase

- ✓ Outsourcing strategy: single global CRO, a multi-CRO model, or a niche CRO?
- ✓ Vendor identification, selection and RFP process

Core Value Proposition: Why Hire a Consultant?

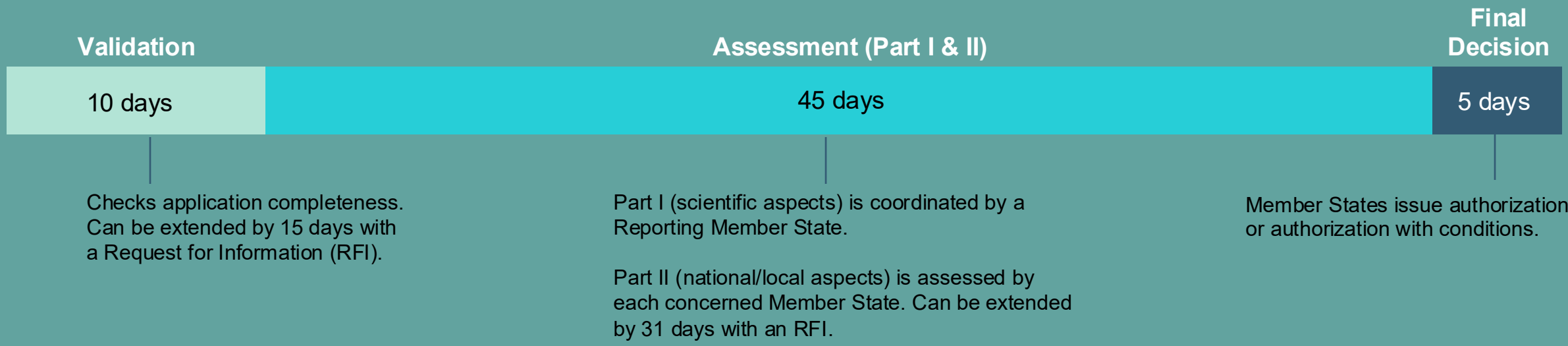
- ✓ Bandwidth and focus: manage the outsourcing process, allowing sponsors to stay focused on science
- ✓ Leverage and objectivity: independent perspective to challenge both CROs and sponsors
- ✓ Process expertise: applying proven frameworks, templates, and best practices
- ✓ Market intelligence: deep knowledge to identify the right partners and regional advantages

Spotlight on Western Europe: Why This Region?

- Advanced capability for modern and complex trials (e.g., ATMPs, basket trials, rare diseases)
- Access to specialized patient populations – rare diseases, oncology subgroups, pre-treated patients.
- Highly experienced investigators and trial sites
- Safe bet for sponsors not being so experienced outside US
- Better healthcare systems than in more Eastern part of Europe
- Lower costs compared to US

Europe & CTIS (Clinical Trials Information System)

- A reliable system which eliminated a good part of the complexity in Europe for CTAs
- Works well for multi-country trials, some speeding up exceptions for single country trials
- Still old memories persist and CTIS education is needed outside Europe



US vs Europe Population Numbers

		
Population	~342 million	~448 million (Post-BREXIT*)
Political	single federal republic	political and economic union of 27 independent nations
Size km²	~ 8.1 million km²	~ 4.2 million km²
Population Trends	still growing, though at a slower rate	growth has been very slow and even declined

Take away

EU > USA

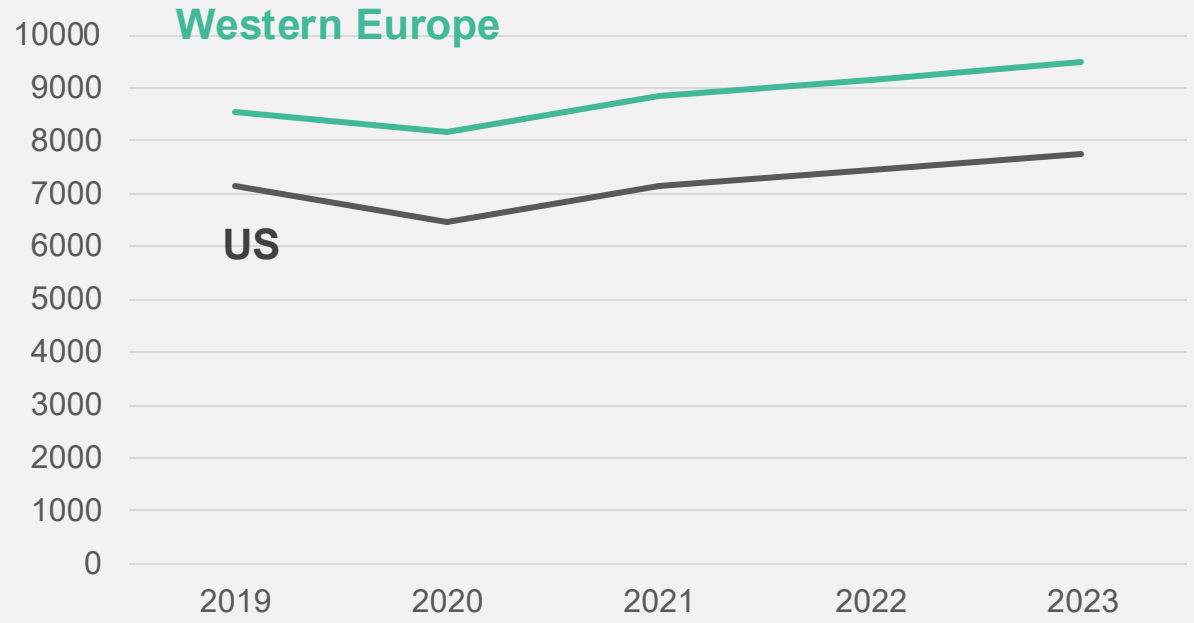
EU more diverse

Population density of the EU is much higher

EU: populations are aging

* Before Brexit (2020), the EU's population was over 510 million. The loss of the UK's ~67 million people reduced the EU's total to its current level of ~448 million. Before Brexit, the population gap was even larger.

Number of Initiated Clinical Trials in US vs. Western Europe*



	US (Approx.)	Western Europe (Aggregated, Approx.)
2019	6,800 - 7,300	8,200 - 8,900
2020	6,200 - 6,700	7,800 - 8,500
2021	6,900 - 7,400	8,500 - 9,200
2022	7,200 - 7,700	8,800 - 9,500
2023	7,500 - 8,000	9,000 - 10,000

There is a broad knowledge base at sites to run clinical trials. The Western European countries often feel like the "safe harbor" outside US for investors and sponsors.

Key Regional Players in Western Europe

- Germany
- France
- Spain
- UK
- Italy

**Source: Estimates based on data from ClinicalTrials.gov and industry reports (e.g., from the IQVIA Institute).*

Operational Excellence, Access, Turnaround Times

Sites

- ✓ Communication with a human touch
- ✓ One point of contact, not a maze of specialists
- ✓ Building trust through active listening

Turnaround Times

- ✓ Realistic expectations for Western Europe
- ✓ Stable networks with trained investigators
- ✓ Proven patient recruitment and diversity rates

Patient Access

- ✓ Lighthouse sites vs. hidden gems
- ✓ Experienced teams for smoother processes
- ✓ Strong cooperation improves enrolment outcomes

Operational Innovations

- ✓ State-of-the-art site equipment (no extra supply needed)
- ✓ Technology, data, and hybrid/decentralized trial models
- ✓ Process efficiencies: start-up, submissions, activation

Western Europe – Case Study

STUDY

Randomized, double blind, multicentre, multinational, placebo-controlled, add-on therapy on top of SoC in emergency department

CHALLENGE

- Sponsor dissatisfied with incumbent CRO (negative feedback from sites, lack of proactivity/flexibility, site initiation delays negatively impacting the recruitment)
- Transfer clinical monitoring of extension phase ILC/CM for European sites.

SOLUTION

- ✓ Understand local emergency care procedures and work hand in hand with the investigator sites' study team to regain their trust, engagement and involvement
- ✓ Team of experienced, dedicated and focused senior CRAs led by a seasoned project manager
- ✓ Recruited 100+ patients, exceeding target (70), compensated for lack in US, entire study recruitment in 9 months, with fewer sites

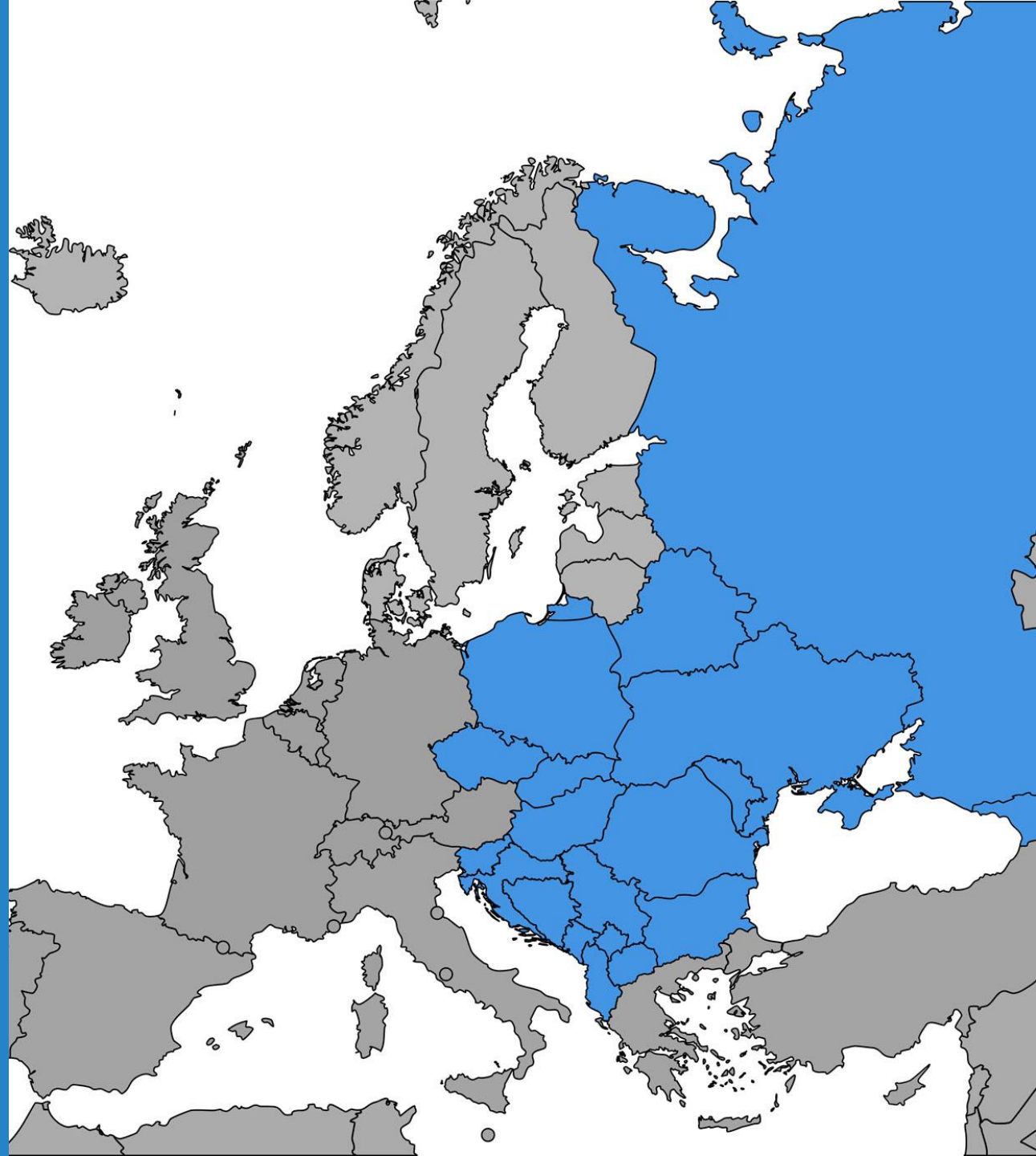
Spotlight on CEE: Why This Region?

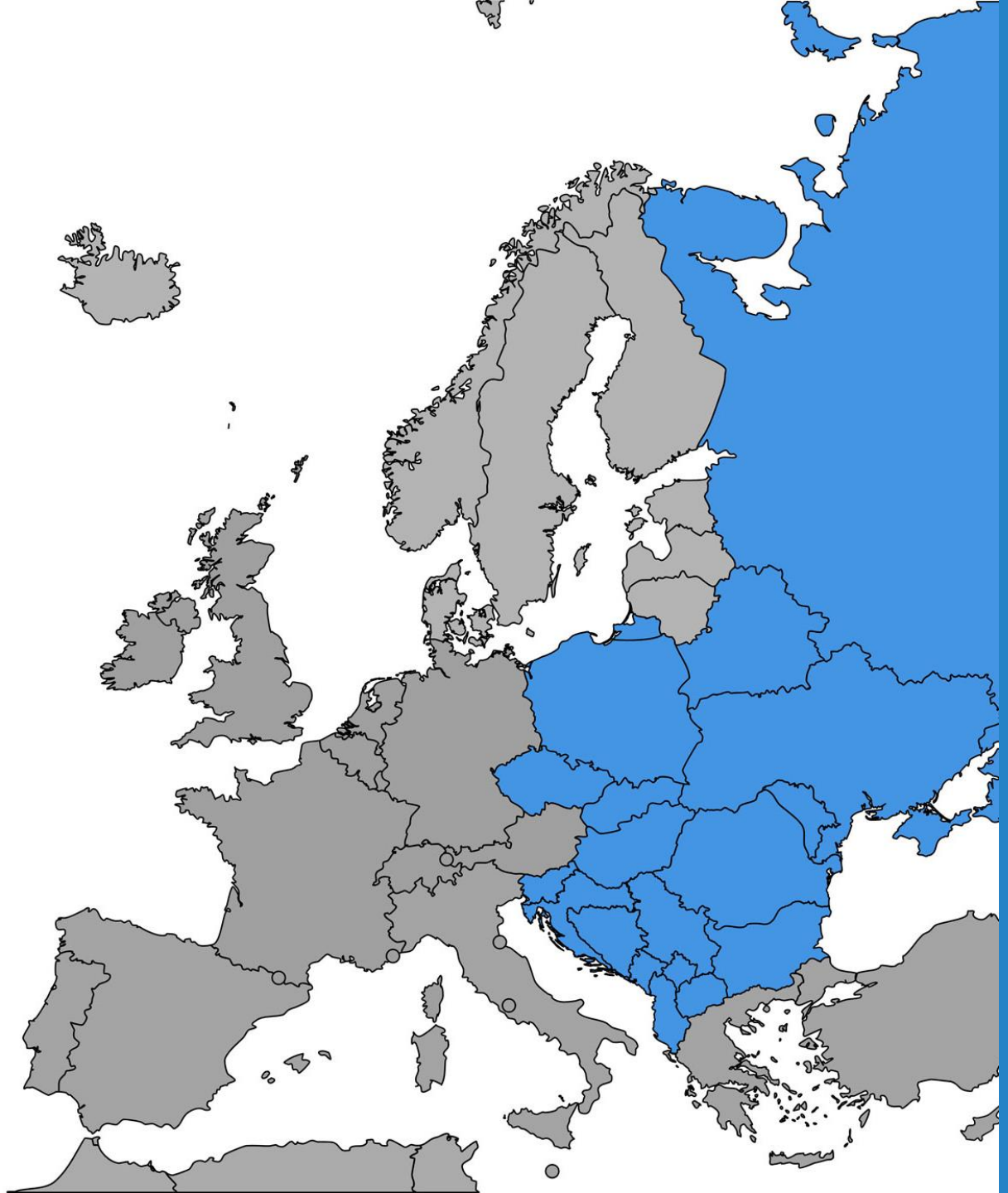
- **Lower study competition**
  Fewer trials than in Western Europe; less saturation across many Eastern/Eurasian countries.

- **Strong patient motivation**
  Patients often join trials to access modern treatments and better care.

- **Access to naïve patients**
  Limited availability of innovative drugs allows access to treatment-naïve populations.

- **High enrolment rates**
  Driven by strong patient interest and availability of healthy volunteers





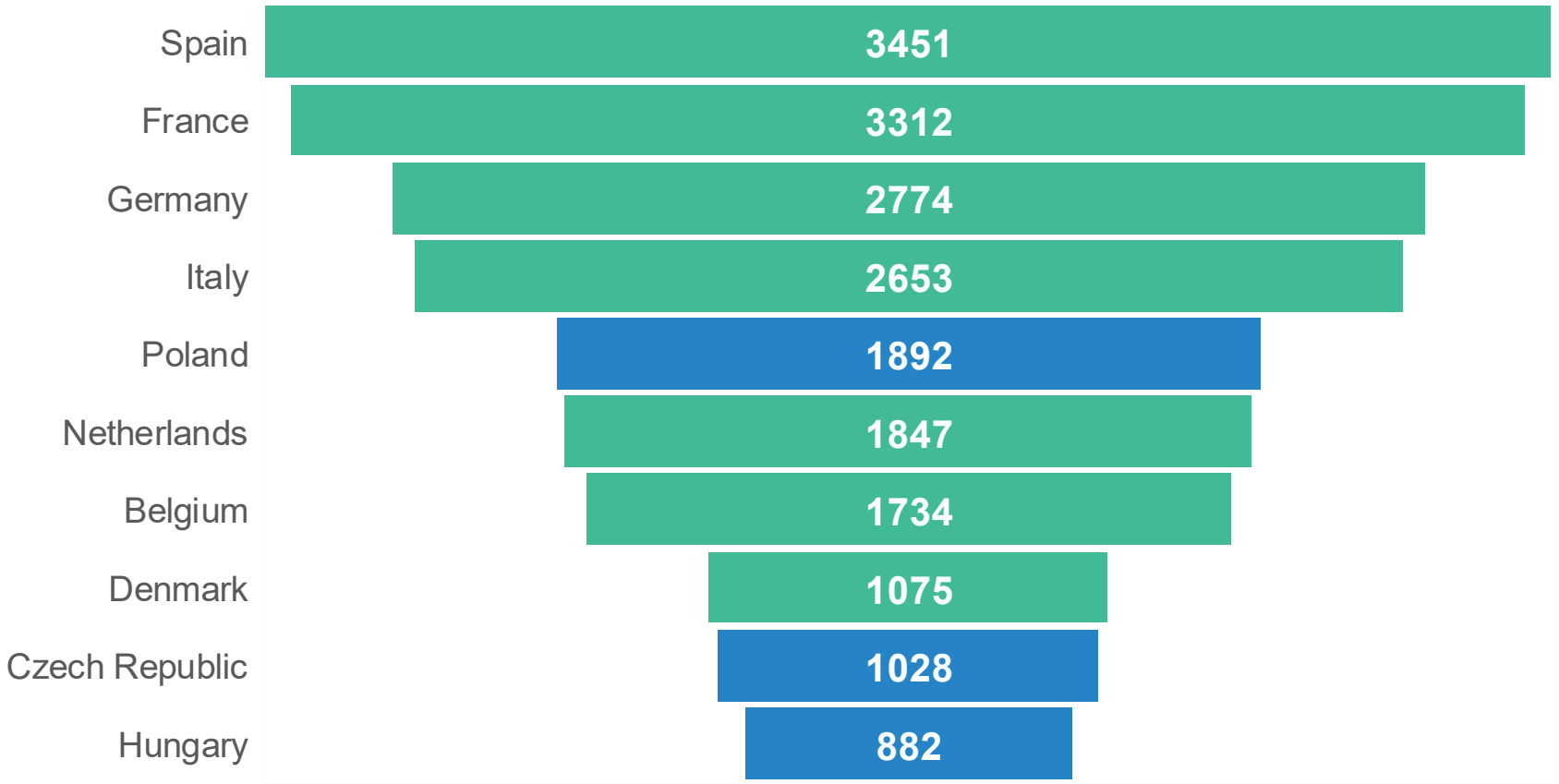
- **Cost efficiencies**
  Lower investigator grants, faster enrolment timelines, and more favorable salary levels.

- **Maintained quality standards**
  Strong education systems and adherence to international GCP. No cutting corners on quality!

- **Centralized patient flow**
  Patients concentrated in key sites, easing recruitment and oversight.

- **Cutting-edge facilities & technology**
  State-of-the-art units, advanced diagnostics, embedded PK/central labs.

Number of Initiated Clinical Trials in 2025*



Data extracted from the EU Clinical Trials Register

Western Europe

Eastern Europe

Top 10 Countries in CEE for Clinical Trials in 2025*

Poland

+	• Population • Regulatory alignment
?	• Saturation • Rising costs

Hungary

+	• Investigator experience • Centralized health systems
?	• Population • Capacity limits

Czech Republic

+	Quality of sites Track record
?	May need to offer premium Rising costs

Romania

+	• Treatment-naïve patients • Cost benefits
?	• Inconsistencies in site quality

Bulgaria

+	• Disease diversity • Lower costs • Growing reputation
?	• Size • Variable infrastructure in rural areas

**Various sources*

Top 10 Countries in CEE for Clinical Trials in 2025*

Ukraine

+	• Strong patient recruitment
?	• War

Serbia

+	• Attractive costs • Decent infrastructure
?	• Smaller hospital capacities • Harmonization and consistency

Slovenia

+	Well-trained investigators High-quality sites
?	Smaller absolute patient numbers Rising costs

Croatia

+	• EU membership • Good trial activity
?	• Very early phase work • Costs higher than other CEE

Estonia, Latvia, Lithuania

+	• Regulatory modernization • Digitalization
?	• Very small populations • Limits for large trials

**Various sources*

Expanding Horizons: CEE & Eurasia Countries to Watch*

Turkey

+	• Population • Varied genetic, ethnic back-grounds
?	• Developing / improving infra-structure

Slovakia

+	• Reasonably strong
?	• Infrastructure & capacity

Bosnia & Herzegovina

+	• Good performance • Solid know-how
?	• Variable pace • Size

Georgia

+	• Quick start up • Good recruitment
?	• Size

Armenia

+	• Regulatory framework improving
?	• Size

**Various sources*

Common Misconceptions About CEE Region

MYTH:
CEE has poor infrastructure

REALITY:
Modern trial sites, digital systems, and compliant labs are standard

MYTH:
Language barriers hinder trials

REALITY:
Most investigators and CRO staff speak fluent English

MYTH:
Regulatory frameworks are unclear

REALITY:
Majority of countries follow EU/ICH-GCP and offer fast, transparent approvals

MYTH:
Data quality is lower

REALITY:
CEE trials routinely meet or exceed global standards for data integrity

MYTH:
Patients are hard to recruit

REALITY:
The region has diverse, untapped, treatment-naïve populations

Eastern Europe – Case Study

STUDY

Ph3, multicenter, adaptive design, acute major bleeding on DOAC therapy with factor Xa inhibitor
Start: Q3/2022
Expected End: Q4/2026
Countries: POL, TRK, GEO, BH
Patients expected: Total: 260, CM/ILC – 137

CHALLENGE

- Joined study 1.5 years after co-CRO.
- Currently (Q4/2025) responsible for 63% of total recruitment

SOLUTION

- ✓ Continuous data-driven monitoring of recruitment trends and proactive adjustments
- ✓ In-depth patient pathway analysis and site support with optimized settings
- ✓ Systematic collection and follow-up of potential patient logs
- ✓ Tailored site-specific recruitment strategies
- ✓ 57 patients enrolled by CM/ILC out of 91 total (in 2 years)

What Mid-sized CROs Bring to the Table

- Personalized Service & Stronger Relationships
- Flexibility & Adaptability
- Cost-Effectiveness
- Faster Decision-Making
- Specialized Expertise

Check for Mid-sized CRO Key Areas:

- Therapeutic Expertise
- Communication & Structure
- Regulatory Knowledge

The CRO Paradox: How Mid-sized CROs Deliver Tailored Solutions

- **100% client focus** – every sponsor gets senior attention
- **Tailored solutions** – listening carefully and adapting to each case
- **Personal site relationships** – leveraging close touchpoints for smoother execution
- **Beyond the big CRO model** – fewer layers, faster start-up, and multiple touchpoints
- **Cultural alignment** – “speaking the culture” and respecting local DOs & DON’Ts

Find the Best Match for Operational Excellence

Patient Pathway

(Centralized/ Non-Centralized)

Countries / Epidemiology

Pre-Treatment?

CTIS / Non-CTIS

Logistics

Know Your Territory!

Q&A Session

Thank you!