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Clinical Development Functional Vs. Full Service *Global or Regional CRO?*

Presented by:

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**Vice Chairman and Managing Director
Manipal AcuNova Ltd,**

April 12nd, 2007

Orlando

www.acunovalife.com

Quality Trial Data, delivered 30% Faster at 30% less Cost

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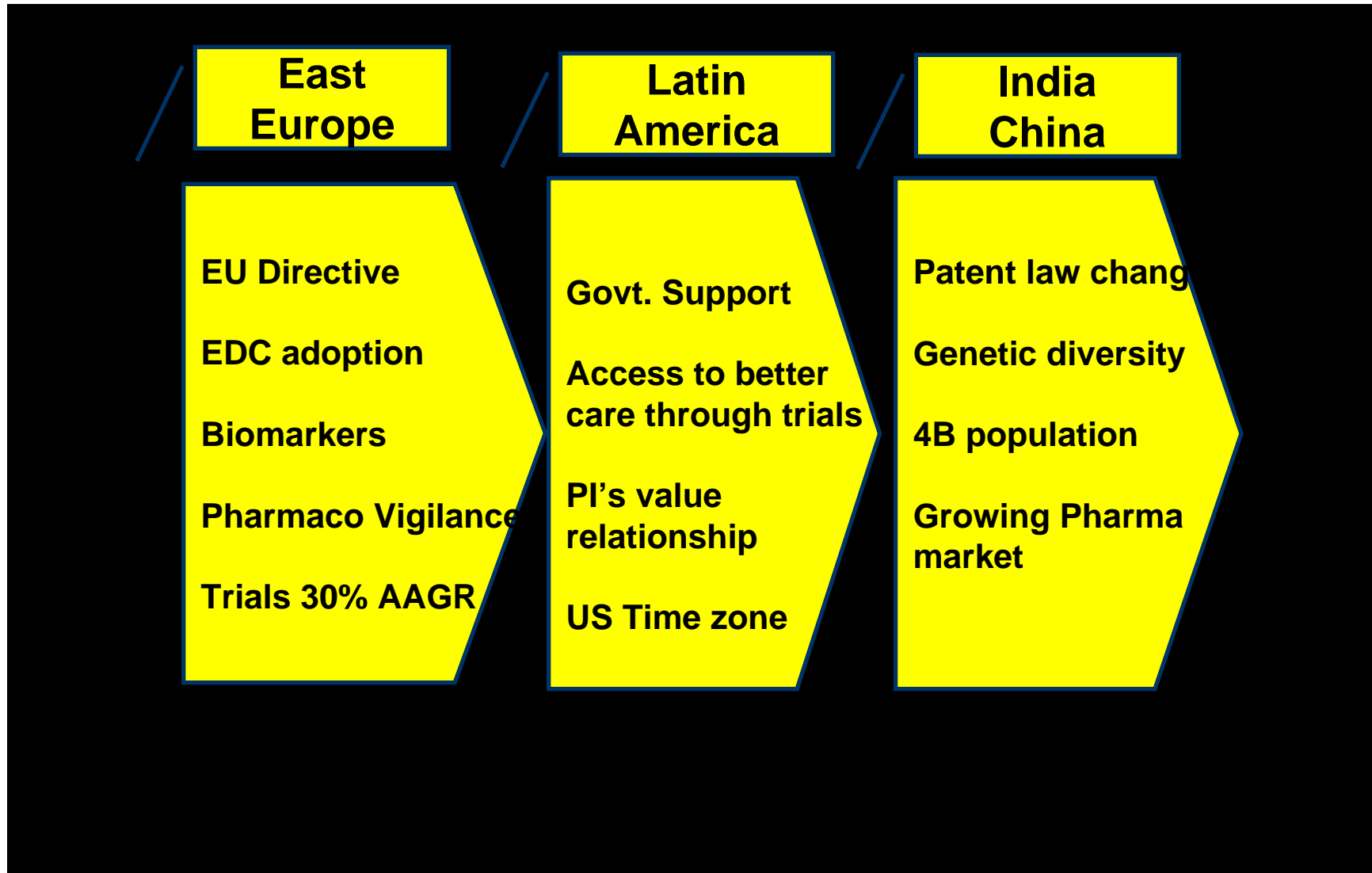
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What will be covered?

- ❖ **Where are Sponsors heading for Clinical Development?**
- ❖ **What is the opportunity and Challenge?**
- ❖ **Can one global solution fit all?**
- ❖ **What can Regional Expert CRO's bring to table?**
- ❖ **Can a string of Regional Expert CRO's deliver better value?**
- ❖ **Case Study**
- ❖ **Takeaway**
- ❖ **Questions**

Where are sponsors interested to conduct trials?



Spain/Portugal in EU and SEA in Asia are also growing as Clinical Development geography



What is common in the new geography?

- ❖ **Speed**
 - Large patient pool**
 - Wide spectrum of diseases**
 - Drug Naïve patients**
 - Investigators & Hospital Sites are qualifying for doing trials**
- ❖ **Cost advantage of over 30%**
- ❖ **Global trial in region reduces local Market registration time.**
- ❖ **Local market for Pharmaceuticals is growing**

*Fast Enrolment with Quality Data
at Competitive cost!*



Regional Differences

- ❖ **Language**
- ❖ **Medical Education System**
- ❖ **Regulation for clinical research**
- ❖ **Health system (s)**
- ❖ **Standard of care**

*Patient Recruitment strategies differ and requires
A sound knowledge of Local Environment*



Challenges in Conducting trials in Regions

- ❖ **Getting Drugs into India/China, delivering to site, IVRS and drug accountability is a challenge.**
Need CRO with local CTSM Service.
- ❖ **Higher loss of lab data reaching global central labs.**
Need Central labs in Regions.
- ❖ **Delay with health Authority**
Latin America...less predictability of authority
China IPR issues
East Europe Diversity of languages
- ❖ **Regional CRO's have better knowledge of requirements and relationships**

Knowledge of local conditions, local solutions
Local relationships key



What are Sponsor's Options for Trials in New Geography?

Criteria	In House	Global CRO	Regional CRO
Trials: Type/No.	large	Global Phase III	Ph I, II, Ph IIIa
Region presence	Top 10 Co's have	Except Quintiles, weak presence	Strong
Management	Central	Central	Local
Registration in Local Market.	Done on priority	Not keen as budget is modest	Registration trials conducted
Speed	Slow	Good / Surprises	Excellent
Cost	Indifferent	Global rates	Economical
Quality	Good	Indifferent	Excellent

Regional CRO's
Deliver Quality, Speed and Cost Advantage



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Sponsor's Challenges

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DISCOVERY • DEVELOPMENT • THERAPEUTICS

**Regional CRO's
offer advantages
not only in cost
but higher speed
compared to
Global CRO's or
doing work in house.**

Sponsors increasingly prefer Excellent Regional CRO.

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Case Study of a Regional CRO Spun off from a University Health System



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Certifications & Accreditation



1st CRO in the country to receive
ISO 9001:2000 Certificate

All Certification in One Year



1st CRO in the country to receive
ISO 27001:2005 Certificate



Our Labs at Bangalore & Manipal are
ISO 15189 accredited By NABL

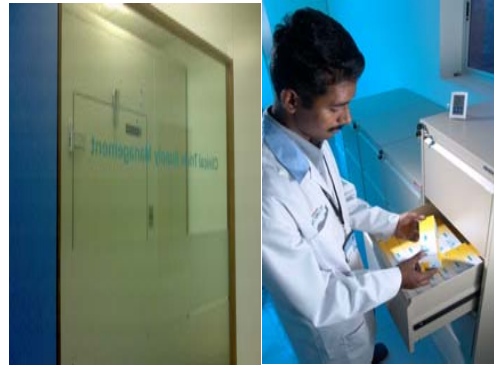
Quality – Our Key Differentiator



Full Service Regional CRO



Phase I



CTSM



Central Lab



CDM



Regulatory Consulting FDA/EU

**Client facing
Personnel in
NJ**

Soon Recruiting Patients in Latin America



Speed and Quality

- Selected by Govt. as CRO to conduct 5 out of 7 clinical trials under govt. funding
- Submission of 30+ PK/PD studies for to US, EU and Indian Regulators
- Completed multi centric Ph 2 Recombinant Cancer drug trial which got MAA
- End to end CRO service for a Phase II trial for a VC funded US Company
- Completed three trials for FDA submission for a EU Co.
- Conducting 27 CRO trials and 71 SMO trials
- Repeat study award from leading global sponsors in Pharma, Biotech and Device Co's
- 174 professionals on Board with excellent regional knowledge to deliver studies for global submission 30% faster and at 30% less cost
- Winner of Proximare 2005 award amongst 33 Indian CRO's as
'India's No.1 Emerging CRO'

*AcuNova has access to Academic Hospital sites and
Credibility with Indian Regulatory Authorities*



Kiecana Clinical Research (KCR) is a European Contract Research Organization which offers a complete range of clinical development and consulting services to the pharmaceutical, biotech and medical devices industries

- *Founded by Marek Kiecana in 1997 as one of the first CROs in Central and Eastern Europe,*
- *KCR specializes in conducting Phase II-IV clinical trials in Europe, particularly in CEE regions*
- *At present KCR belongs to the leading CROs in CEE regions.*

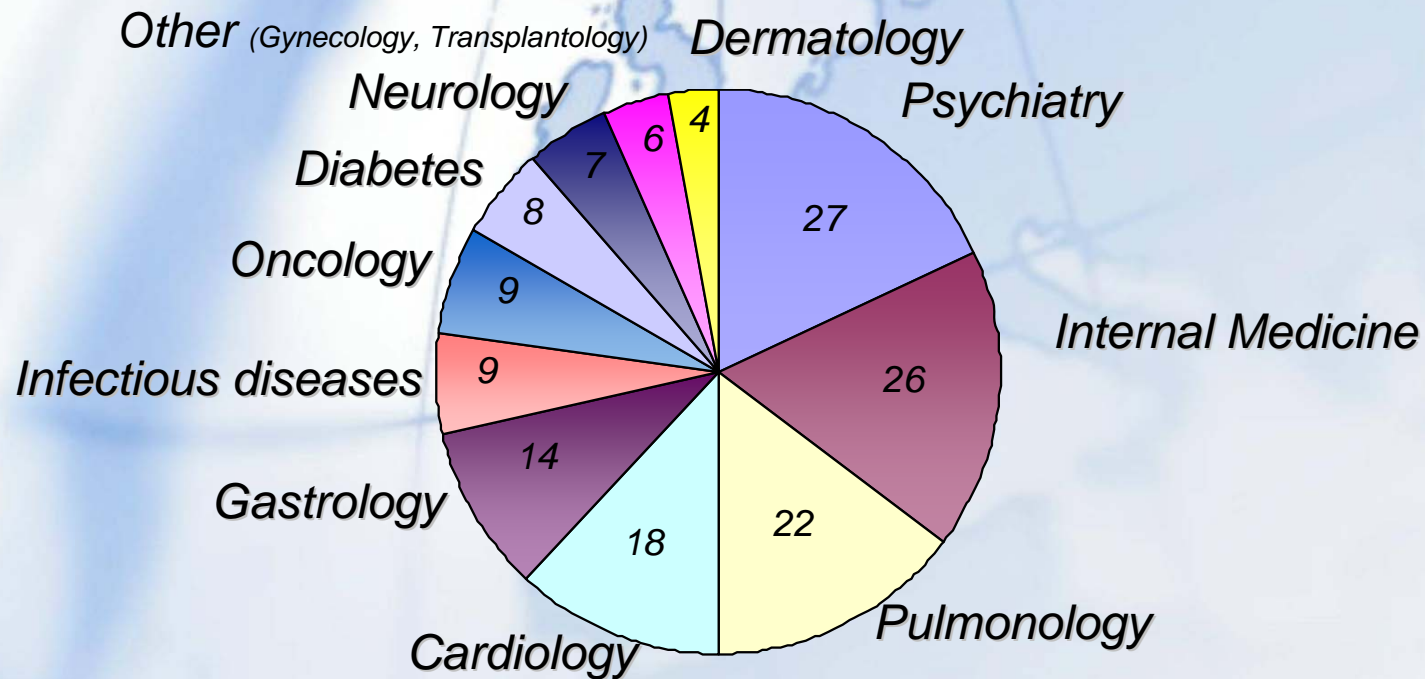


Where we operate

Access to wide number of sites and patients



KCR has performed over 150 studies involving 7.182 centers in the following therapeutic areas



***The KCR's Quality System is certified by D.A.S.
CERTIFICATION Ltd. using ISO 9001:2000***

Our dedicated QA professionals make sure that clinical studies are conducted in compliance with ICH GCP, local regulations, Sponsor and KCR SOPs and study contracts



**The First CRO in the
CEE region to
receive
ISO 9001:2000
Certificate**



**KCR received accreditation
of
French Ministere Education
Nationale Enseignement
Superieur Recherche**

**The First & only CRO in
the CEE region to receive
Status of R&D Company**



Our Mission Statement

“We understand you better”

How KCR “understands you better”

Understanding Customer:

Each customer, regardless of size, is important to us

1. We are **flexible** – we can adjust promptly to customer’s needs
2. We make **decisions fast**
3. We are **experts on CEE** clinical research mkt
4. We **know CEE local conditions**

Understanding Investigators:

Our Investigators are experts in health care systems in CEE

1. We are **strongly connected** to health care environment
2. We **help the investigators** to resolve the research related issues
3. We cooperate with the investigators on **providing patients with safe and ethical examination and treatment**

Understanding KCR Team

1. we **listen and talk** with our employees
2. we **discuss** our short and long term objectives
3. we **set career paths** to meet their aspirations
4. we **invest in personnel** development

References

„KCR seems a well managed CRO company, with highly qualified staff. We have never experienced any problems with schedules and timelines. I would not hesitate to recommend Kiecana Clinical Research as reliable CRO, capable to work even on complex clinical studies.”

Medical Director MSD

“We admire a lot the job done by KCR due to excellent quality, open attitude for innovative solutions and commitment to common objectives.”

Lilly Medical & Regulatory Director

“KCR is a well managed CRO, with qualified personnel and appropriate Standard Operating Procedures.”

Scientific Director of Bayer CEE

“KCR appears to be a reliable company that always keeps to the schedules and timelines KCR is strongly focused on good contact with the investigators.

The work done by KCR with our studies is really impressive, both as far as quality, time and recruitment of subjects are concerned”

Medical Scientific Affairs Manager Schwarz Pharma

„We are fully satisfied with the professionalism of services offered by KCR. In particular, their flexibility despite still changing legal and economic conditions, as well as their creativeness and board-mindedness to new ideas are really impressing.”

Medical Director of Sanofi

Full text of references and list of our clients available on request

Why KCR ? The answer is...

- ▶ *The most effective CRO in CEE regions*
- ▶ *10 years of experience in clinical trials*
- ▶ *Access to wide number of sites and patients*
- ▶ *Deep knowledge of local regulatory process – faster study registration*
- ▶ *High quality, confirmed by references and ISO certificate*
- ▶ *Verified strategies for fast and targeted recruitment*

***By choosing KCR you can speed up your
product development and
lower R&D expenses***

Quality Leadership



AcuNova is ICH-GCP Compliant
DCGI Inspected | 25 client audits
NIH Accredited IRB



Proximare Award
India's No. 1 Emerging CRO

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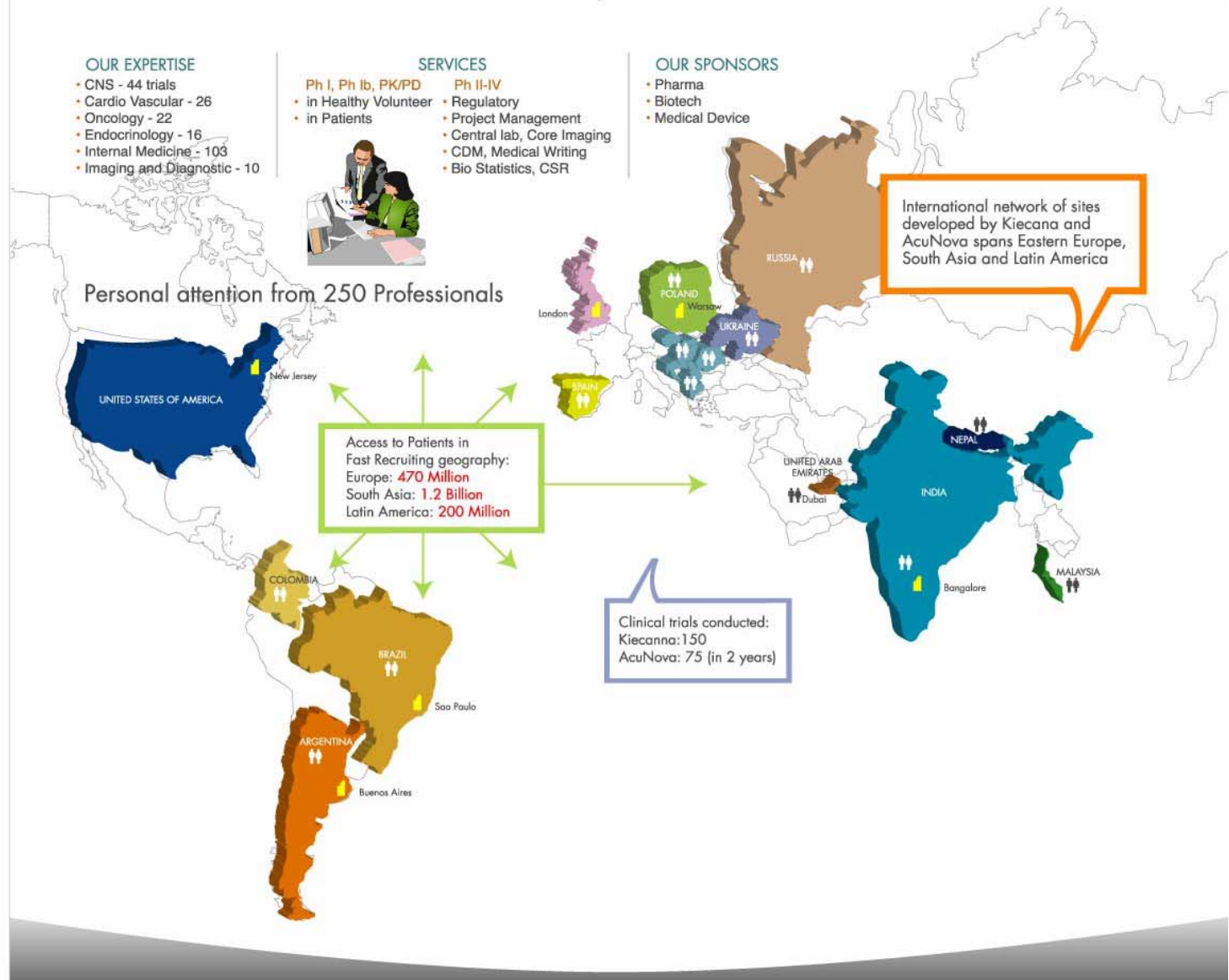
Kiecana is ICH GCP Compliant
ISO Compliant

Sites Inspected by Polish Regulator
EU and FDA

www.kiecana.com

AcuNova Life Sciences + Kiecana Clinical Research

Your Regional Expert CRO For Quality Trials, on Time at Competitive Cost
in India, East Europe and Latin America



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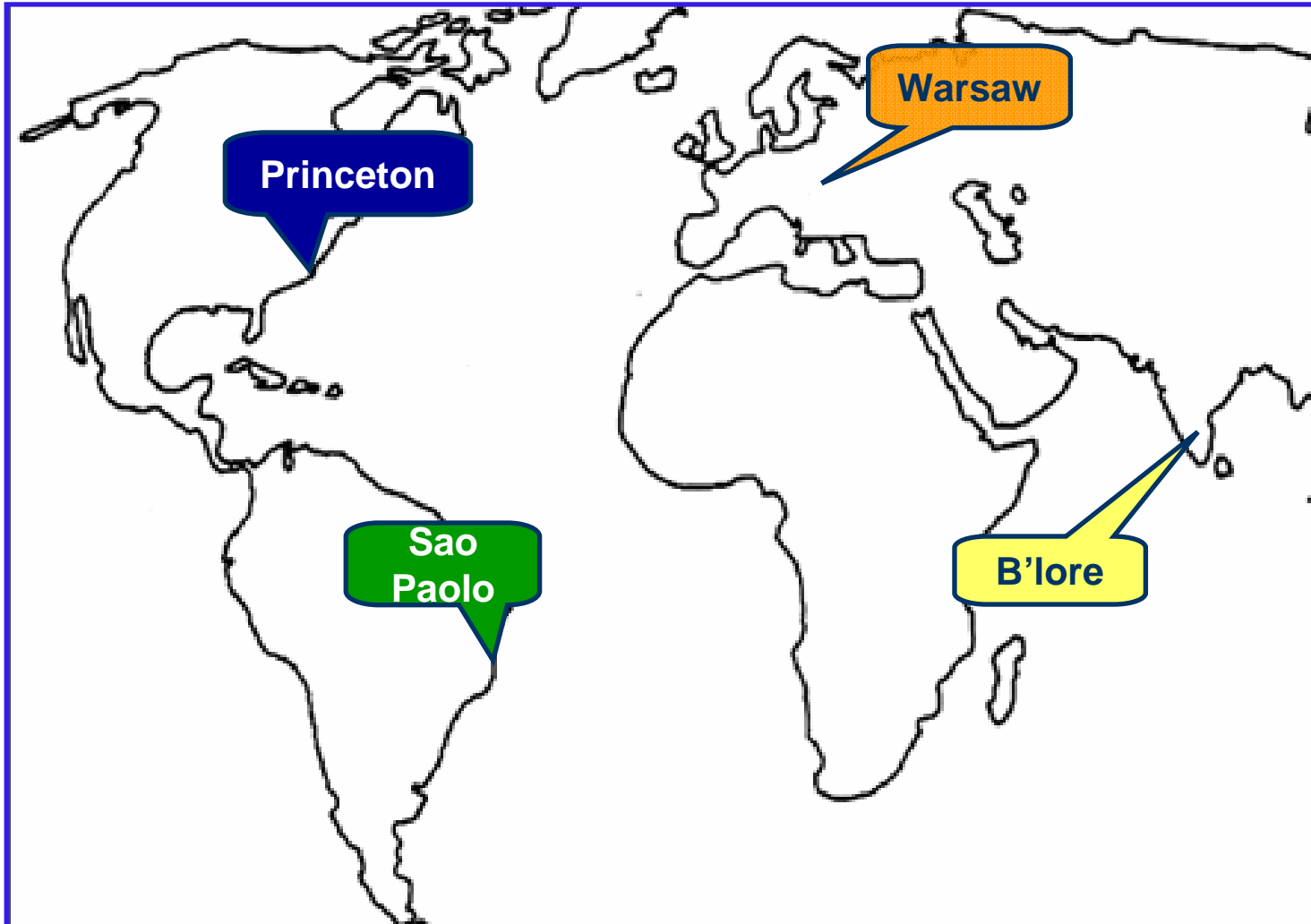


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Do You want a Vanilla Global CRO

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DISCOVERY • DEVELOPMENT • THERAPEUTICS



Or a Necklace of Excellent Regional CRO's ?

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Takeaway

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- ❖ **Regional CRO's can contribute Quality data 30% faster at 30% lower cost**
- ❖ **Make a choice...Global or Regional CRO**

Thank You

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