



Frankfurt



Bangalore

Where is Your next Clinical Trial?

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Manipal



What will be covered?

Generic or a Bio-similar?

India, East Europe, China, Latin America

India Opportunity

Competency Criteria for study

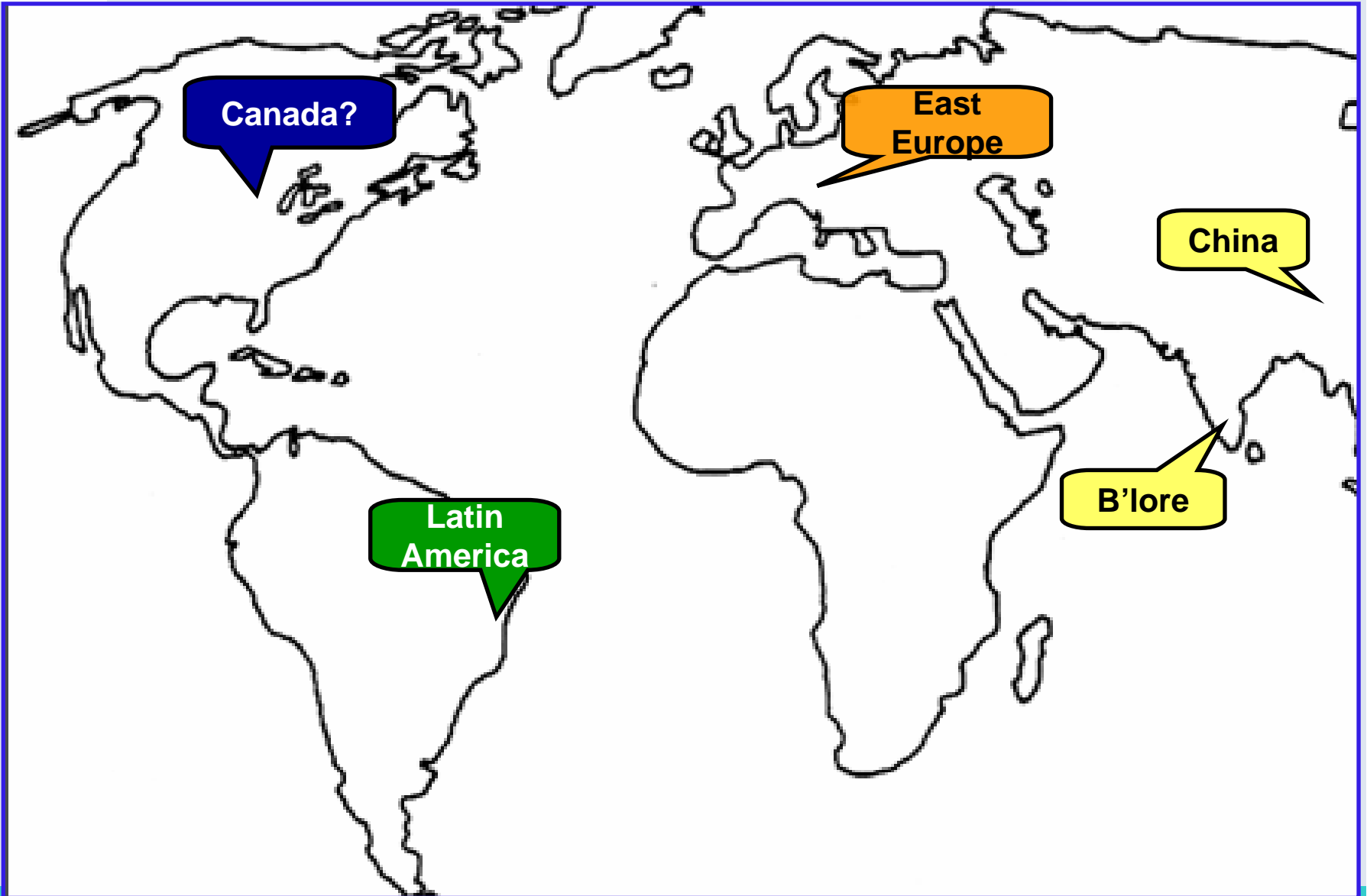
Challenges in Conducting Studies?

Case Study –ECRON ACUNOVA

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Wide Choice for sponsor



Incorrect choice can be costly!



China, East Europe & Latin America Vs. India

Criteria	India	East Europe Lat. America	China
Race Type	Caucasian	Caucasian/African	Mongoloid
Population	1.1B	200/300M	1.5B
Regulator	one	5-6	one
Language	English	2-5	Translation
Time Zone	Too Far	Same as EU/US	Same as Japan

ICSE FFM/EA/MAL/290908V1

***Latin America 50% of people in top 2 cities
China leads in Pre-Clinical. India in potential & Speed***



Generic and Bio Similar Study Needs

❖ **Generic- studies: Healthy volunteers**

Number of volunteers

Regulatory inspection

❖ **Generic studies: Patients**

Speed to file 505 (b) (2) in USA

Oncology, CNS and Cardiovascular

PK/PD & Patient study experience

❖ **Bio Similar- Clinical trials**

Regulator's view

Bio Pharma, Early Stage Study and Pharmaco vigilance

***For Healthy volunteer Studies India is obvious
Patient studies need deeper evaluation***



India Opportunity

❖ Speed

Large Caucasian patient pool

Wide spectrum of diseases

English is language of Investigators & Hospital Sites

Standard of care is western

❖ Regulatory

Documents submitted in English to DCGI/ EC / Sites

ICH-GCP guidelines is legal requirement

❖ Cost advantage of over 30-40%

❖ Global trial in India reduces Indian Market registration time.

Fast Enrolment at Competitive cost!

Quality depends on CRO



Criteria for Studies

Criteria	Healthy Volunteer	Patient Studies	Bio Similar
Regulatory Inspection	Critical	Desirable	Desirable
PK/PD & early stage CRO	PK/PD is sufficient Excellent	Critical	Early Stage exp Critical
Therapy or Domain exp	Desirable	Critical	Bio Pharma exp critical
Pharmaco Vigilance	Not required	Not required	important

***Country of study depends on
Availability of CRO's with required competence***



Criteria Vs Geography

Criteria	Healthy Volunteer	Patient Studies	Bio Similar
Regulatory Inspection	Critical	Desirable	Desirable
PK/PD & early stage CRO	PK/PD is sufficient Excellent	Critical	Early Stage exp Critical
Therapy or Domain exp	Desirable	Critical	Bio Pharma exp critical
Pharmaco Vigilance	Not required	Not required	important
	India Latin America	India East Europe	East Europe India

***India and East Europe
Present interesting choice***



Sponsor's Challenges

- ❖ **Will FDA or EU accept 70% recruitment from India/East Europe and 30% from America's/EU?**
Can CRO contribute to regulatory strategy with FDA/EU?
- ❖ **Who will do the integration of geographies? Can recruiting geographies, use common SOP's?**
- ❖ **Who will recruit 30% of subjects in EU and Americas?**
- ❖ **Distance & Time Zone of recruiting geography**
Does CRO have client facing persons in your time zone?
- ❖ **Is CRO Competent to offer required combination of services; PK/PD, Patient Study experience, Central Lab, CDM...**

***Some Regional CRO's
have Geared up to this Challenge***



**Deep Regional
Competence and
Multinational
Presence**

EUROPE

**Access To Patients in
India & East Europe
Helps Recruitment**

INDIA

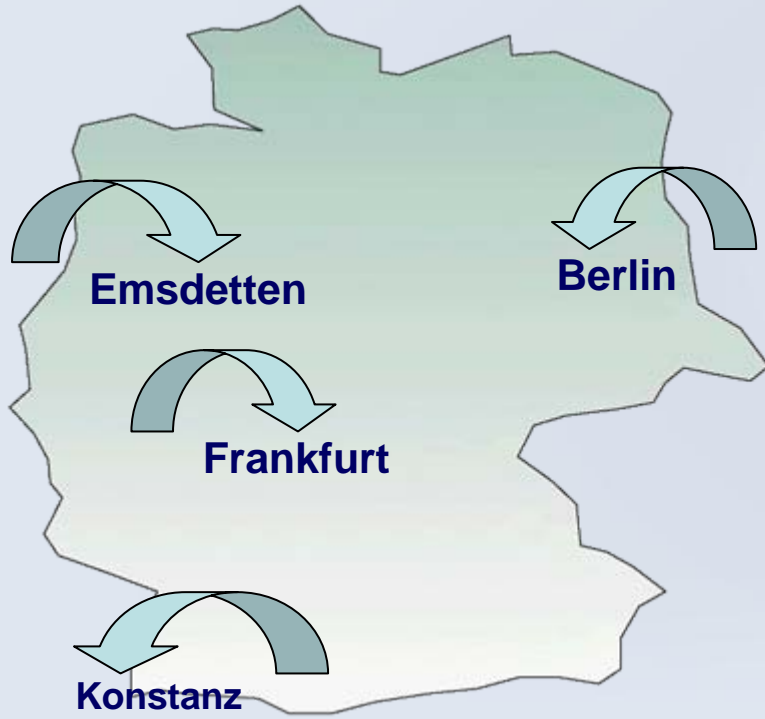
**Client Benefit by
Combination of
Cultures and
Capabilities**

Quality Study on Time at Competitive Cost & Personalized Service

***Combines the best of East & West
Up to 50% Cost Competitive in India compared to West Europe***



Direct Clinical Operation in Germany, India, East Europe



East Europe	Company	Comment
Czech Republic, Slovakia	ECRON The Czech Expert s.r.o.	Active in CZ and SK since 1992 Office in Prague
Ukraine	ECRON LLC	Active since 2005, office in Keiv
Poland	ECRON sp. z.o.o.	Active since 2001, office in Warsaw

Can conduct Indo European Studies with one Project Manager



Your Expert CRO in India

- **Strategic Consultancy**
- **Regulatory & Pharmacovigilance**
- **Phase I** 144 beds,
6 First-in- Man ICU
- **Phase II-IV** Full Service in
India & Europe.
- **Central Lab** ISO/CAP certified
at Bangalore.
Comaptible with
LKF, Kiel, Germany
- **Biometrics**

India Trials

- **Phase I** 90 studies completed
Frost & Sullivan award
- **Phase II-IV** 50th trial launched
19 trials completed
No. 1 CRO award
- **Audited by US FDA**
- **Audited by WHO**
- **Accredited by ISO & CAP**

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One project manager can combine PK/PD, Lab, Clinical Trial for you



India's No.1 CRO by Proximare Inc.

2007

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**Partner of Choice in BioAvailability
BioEquivalence Studies**

Presented to

Manipal Acunova

David Frigstad
CHAIRMAN

Anoop Zutshi
PRESIDENT



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