Practical considerations on medical device clinical trials in Georgia, a former Soviet Union country

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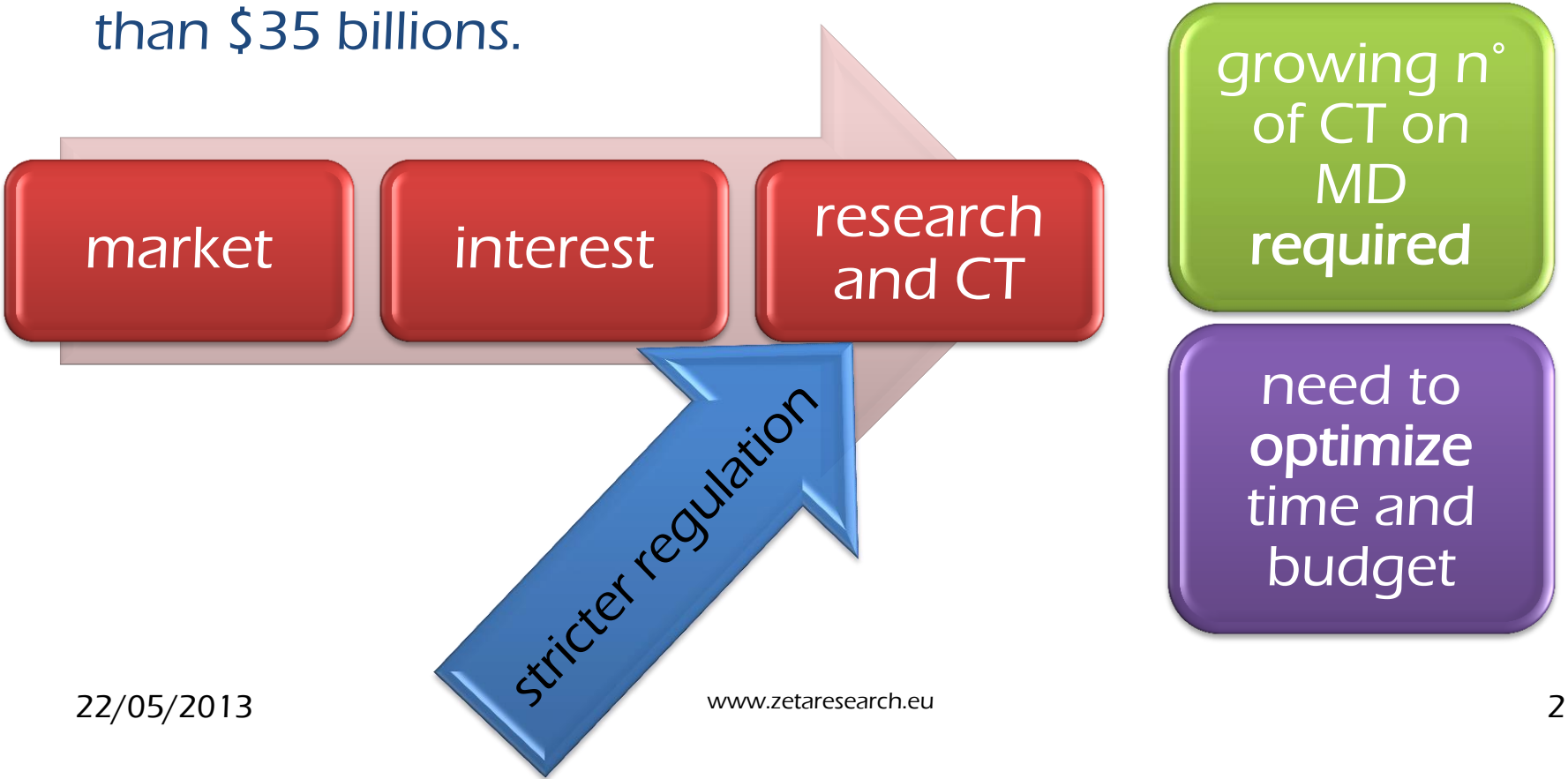
Clinical Trials (CT) on Medical Devices (MD)

- Medical device global market is estimated to be $454 billion worth by 2014 .
- Pharma and (main) MD research is considered to reach more than $35 billions.



OUR EXPERIENCE: .... what about trying abroad?

Abroad = outside EU borders, "growing countries" someway close to EU

TIME

- Could it be quicker?

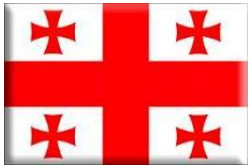
MANAGEMENT

- Could it be easier?

MONEY

- Could it be less expensive?

OUR EXPERIENCE: …. why Georgia?



NOT TOO FAR…

- Close to EU borders

OUR EXPERIENCE: .... why Georgia?

NOT TOO FAR...

- Close to EU culture:
  - Democratic republic (indipendent from USSR since 1991)
  - Close to occidental cultural level
  - Open borders and open-mind

About going abroad...

What we were SUPPOSED to find....and what we've found:

No/low regulation on MDCT

"Essential" but clear regulation

- Exhisiting regulation concerns only medical products (drugs)
- MoH has few but clear "rules" and strict limits for MD trials.

About going abroad…

What we were SUPPOSED to find….and what we've found:

Absent Competent Authorities (CA)

Effective and efficient presence of CA

- MoH approval for Investigational Products (IP) always required
- Response is provided within 21 days from request
- Only Georgian society can apply for approval
- Ethical Committees work on flexible session calendar

About going abroad…

What we were SUPPOSED to find….and what we've found:

Less strict ethical requirements

Same ethical evaluation approach

- Same requirements and documentation as EU for ethical approval
- Great attention to investigational products

About going abroad…

What we were SUPPOSED to find….and what we've found:

Lack of skilled personnel

Qualified medical personnel

- Qualification level in most clinics is comparable at European level
- Fluent English is commonly spoken among medical personnel
- Slight differences in ordinary medical practices can be met

About going abroad…

What we were SUPPOSED to find….and what we've found:

Deficient infrastructures

Modern and westernized structures

- Clinics are private and modern ones, very close to occidental standards
- All clinics have high speed internet !

About going abroad…

What we were SUPPOSED to find ….and what we've found:

Political instability

Stabile and open-minded society

- Despite recent history, most of Georgia is a safe and stable country
- Massive open-mind towards foreign people and models

About going abroad…

What we were SUPPOSED to find ….and what we've found:

Low attributes of patients

Positive attitude to be involved in CT

- No reimboursement for expensive bio-tech is provided to citizens: patients are glad to be enrolled in CT to receive "new" treatments
- Difficulties in patients' retainment in the study

About going abroad…

- Lack of self-explaining English informations available
- [illegible]
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need for

Strong local PARTNERSHIP and sound knowledge of PROCEDURES

So...what kind of saving?

strong and consolidated local PARTNERSHIP and PROCEDURES

Quicker start-up

GCP application

High DATA QUALITY

TIME-SAVING

ECONOMIC SAVING up to -30%

OUR EXPERIENCE: some data

4 Clinical Trials in Georgia in 2012/13:

- On class I and II Medical Devices
- Post-market (commercialized in EU)
- Adult and pediatric population
- Ophtalmology, reumatology, allergology
- 2 closed, 1 ongoing, 1 planned
- Local partnership + Centralized data management

Summing up…

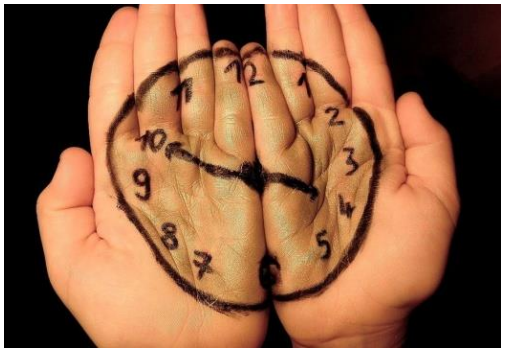
CONS

- Need for a local partnership / consolidated experience (language, regulations, MoH, custom)
- Remote management

PROS

- Easier recruitment
- Quicker EC approval and defined MoH response time
- **GCP standards** known and applied
- **Economic saving**

THANK YOU
FOR YOUR ATTENTION...



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