

Conducting Clinical Trials in Slovakia: Incentives and Opportunity for Western Corporations

Adrea Widule University of Scranton

312,965 TRIALS GLOBALLY

96,237 in the United States

104,422 in Europe

1,653 in Slovakia (April, 2016)

Note. Adapted from “International Clinical Trials Registry Platform (WHO, 2016)

Retrieved from:

<http://apps.who.int/trialsearch/ListBy.aspx?TypeListing=2>

WHAT ARE CLINICAL TRIALS?

Who conducts them?

What's the drug development process?

Phase I

Small group, mostly healthy volunteers (20-100 patients)

Few months-year



Phase II

Group of volunteers who have the disease being studied (50-300)

Several months-2 years



Phase III

Huge patient populations, expansive global studies (300-3,000)

1-4 years



Note. Adapted from “Step 3: Clinical Research” (FDA 2015)

Retrieved from <http://www.fda.gov/ForPatients/Approvals/Drugs/ucm405622.htm>

“

“The average cost to develop and gain marketing approval for a new drug—pegged at \$2.558 billion”

-Journal of Health Economics, 2016

Advantages of running a trial in Central Eastern Europe?

- Patient Access
- Speed
- Quality

Patient Access

HISTORY

The history of centralized health systems have resulted in large medical centers with numbers of patients who can be quickly enrolled in clinical trials.

SPECIALIZED HEALTHCARE

Access to innovative and specialized treatments takes longer to receive.

- Nemeec, J., Spacek, D., & de Vries, M. (2015).

Quality

MOTIVATED PATIENTS

Those enrolled have a greater need for access to specialized treatment and are more engaged.

HIGHLY TRAINED INVESTIGATORS

Requirements for specialists involved in clinical studies historically higher.

RESULTS

“Doctors spend a lot of time working on the trials and the data is very good.”

*-Dr. Juraj Petrinc
(EuroScientist journal, 2014)*

FDA's publicly accessible Clinical
Investigator Inspection List,

	Western Europe	Central and Eastern Europe	USA	Other	Total
NAI	148	128	1711	164	2151
	36.9%	55.7%	44.3%	43.6%	44.2%
VAI	235	100	2061	206	2602
	58.6%	43.5%	53.4%	54.8%	53.5%
OAI	18	2	86	6	112
	<u>4.5%</u>	<u>0.9%</u>	<u>2.2%</u>	1.6%	2.3%
Total	401	230	3858	376	4865

Abbreviations: NAI, no action indicated; VAI, voluntary action indicated; **OAI, official action indicated Findings.** Caldron, P. H., Gavrilova, S. I., & Kropf, S. (2012).



ACCESS + QUALITY = SPEED

Shorter start-up times massively cut costs, and quality data leads to faster approval.

A black and white photograph of a calm body of water, possibly a lake or sea, with mountains in the background. A small, dark structure, possibly a pier or a small building, is visible on the right side of the water. The sky is overcast with light clouds. The entire image is framed by a white border.

Slovakia

Data pulled from EU Clinical Trials Register, Center
Watch and the World Health Organization
International Clinical Trials Registry- April 2016

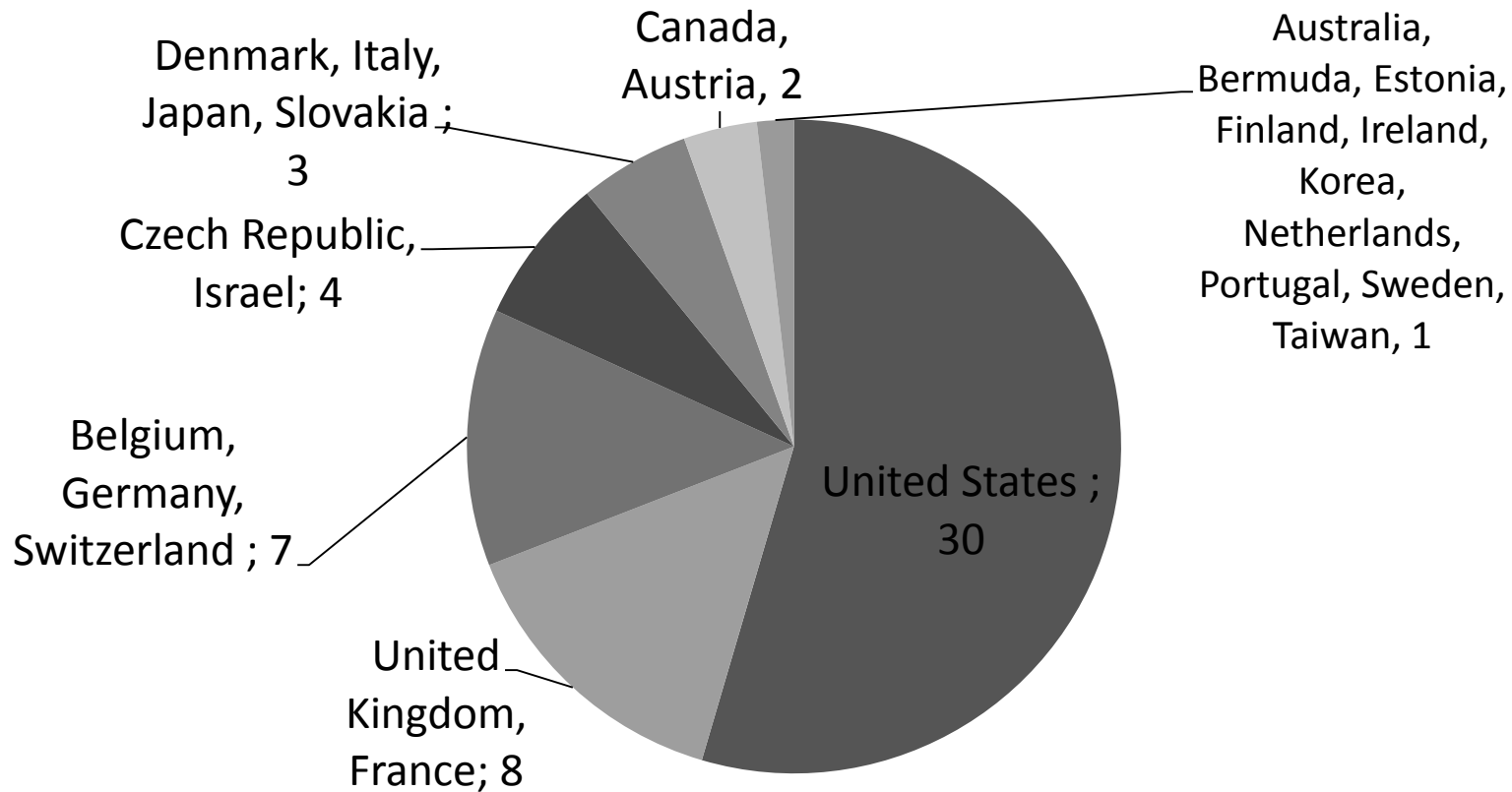


400+ studies
actively enrolling

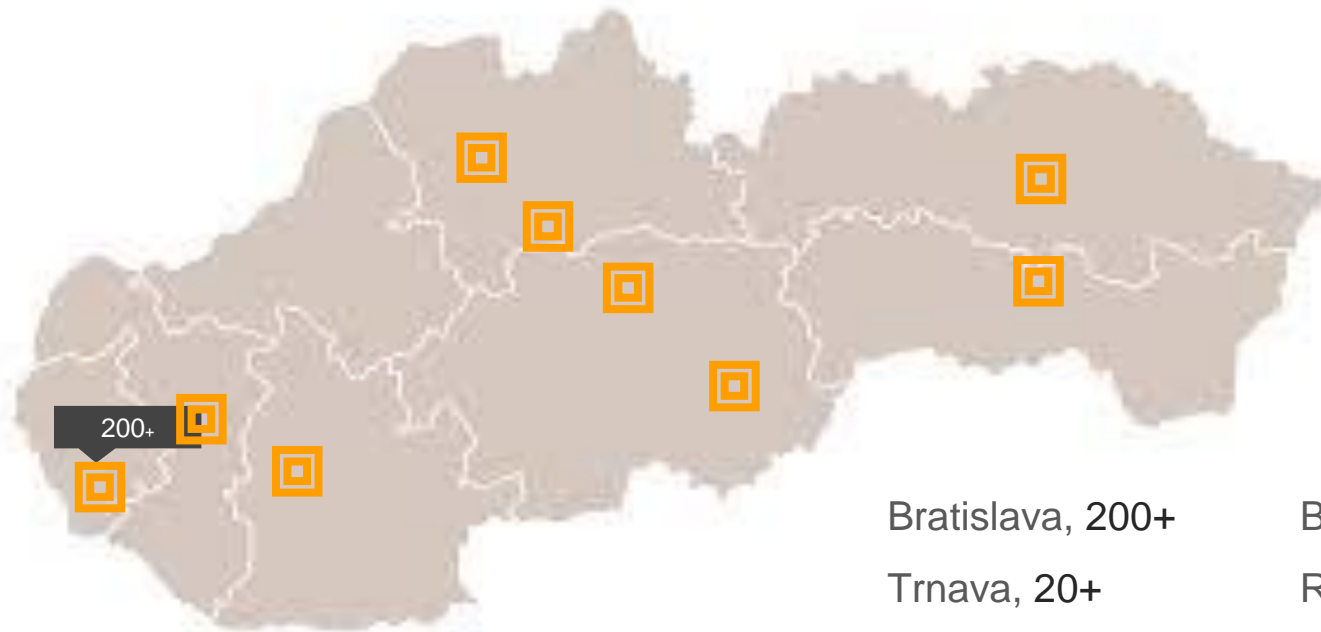
700+
total sites

across 40+
cities in Slovakia

101 Different Sponsors



Cities with the most sites



200+

Bratislava, 200+

Trnava, 20+

Nitra, 50+

Žilina, 50+

Martin, 20+

Banská Bystrica, 50+

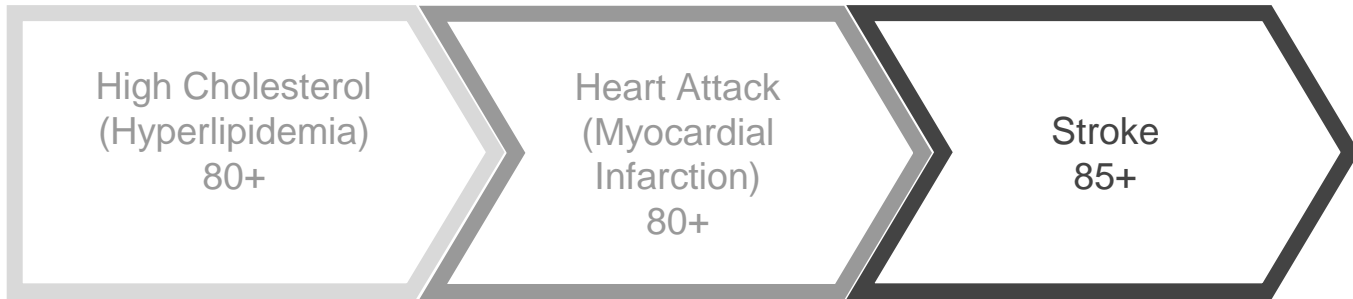
Rimavská Sobota, 20+

Košice, 50+

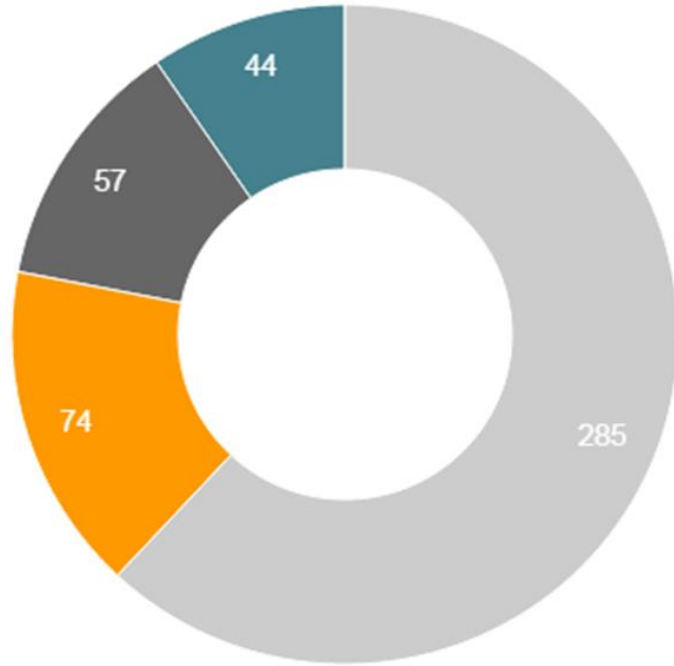
Prešov, 30+

Top Indications

- (290+) Heart Disease
- (70+) Ulcers
- (65+) Cancer
- (60+) Kidney Disease
- (30+) Asthma
- (30+) Diabetes Mellitus, Type 2
- (20) Epilepsy
- (15) Blood Disease



Top Sponsors



● Pfizer ● Novartis ● AstraZeneca ● AbbVie



Implications & Conclusion

THANKS!

Any questions?

Sources

- ❑ **Caldron, P. H., Gavrilova, S. I., & Kropf, S. (2012)**. Why (not) go east? Comparison of findings from FDA Investigational New Drug study site inspections performed in Central and Eastern Europe with results from the USA, Western Europe, and other parts of the world. *Drug Design, Development and Therapy*, 6, 53–60. <http://doi.org/10.2147/DDDT.S30109>
- ❑ Central and Eastern Europe present both challenges and opportunities for Canadian pharma industry. (2015, December 17). Retrieved April 03, 2016, from <http://www.clinicaltrialsarena.com/news/operations/central-and-eastern-europe-present-challenges-and-opportunities-for-canadian-pharma-industry-says-expert-4756600>
- ❑ Clinical trials Eldorado based on quality, not cost - **EuroScientist Journal**. (2014, November 26). Retrieved April 3, 2016, from <http://www.euroscientist.com/clinical-trials-eldorado-based-quality-not-cost/>
- ❑ Clinical trials for Slovakia. (2016, April 12). Retrieved April 12, 2016, from <https://www.clinicaltrialsregister.eu/ctr-search/search?query=slovakia>
- ❑ **International Clinical Trials Registry Platform (WHO)**: List by Regions/Countries. (2016, April 14). Retrieved April 17, 2016, from <http://apps.who.int/trialsearch/ListBy.aspx?TypeListing=2>
- ❑ **Journal of Health Economics**, Tufts Center for the Study of Drug Development. (2016, March 10). Retrieved April 15, 2016, from http://csdd.tufts.edu/news/complete_story/tufts_csdd_rd_cost_study_now_published
- ❑ **Nemec, J., Spacek, D., & de Vries, M. (2015)**. Coordinating Healthcare Under a Pluralistic Health Insurance System: The Case of Slovakia. *Transylvanian Review Of Administrative Sciences*, 11(45), 168-184. Retrieved from <http://rtsa.ro/tras/index.php/tras/article/view/444>
- ❑ Slovakia Clinical Trials. (2016, April 12). Retrieved April 12, 2016, from <https://www.centerwatch.com/clinical-trials/listings/location/international/Slovakia/>
- ❑ U.S. Food and Drug Administration. **Step 3: Clinical Research** (2016, November 23). Retrieved April 15, 2016, from <http://www.fda.gov/ForPatients/Approvals/Drugs/ucm405622.htm>