



AKADEMIA
LEONA KOŹMIŃSKIEGO

Clinical Research Market in Poland



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Agenda

- Why pharma R&D?
- Clinical trials introduction
- Clinical trials market in Poland
- Opportunities and challenges
- Global vs. local clinical research market value
- Clinical trial market employees

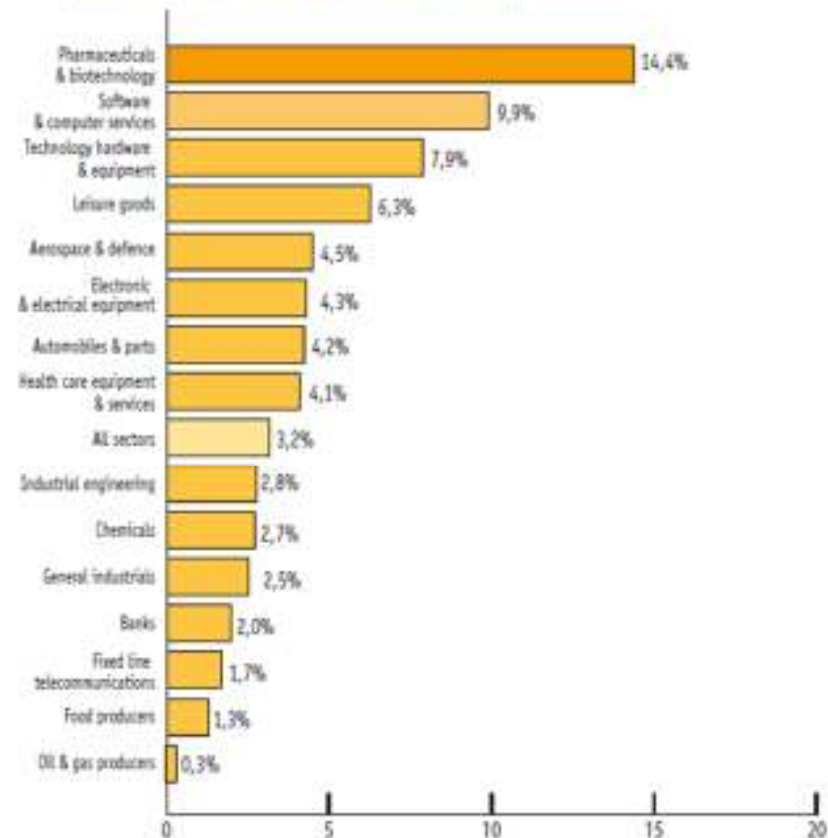
Business R&D investments

‘Pharmaceuticals and biotechnology sector amounts to 18,1% of total business R&D expenditure worldwide’.

According to the 2013 EU Industrial R&D Investment Scorecard

Source: The Pharmaceutical Industry in Figures, Key Data, 2014, European Federation of Pharmaceutical Industries and Associations

RANKING OF INDUSTRIAL SECTORS BY OVERALL SECTOR R&D INTENSITY
(R&D AS PERCENTAGE OF NET SALES – 2012)



Note: Data relate to the top 2,000 companies with registered offices in the EU (527), Japan (353), The USA (658) and the Rest of the World (462), ranked by total worldwide R&D investment (with R&D investment above € 22.6 million)

Source: The 2013 EU Industrial R&D Investment Scoreboard, European Commission, JRC/DG Research & Innovation

Pharma Industry R&D investment in Europe

	EFPIA 2012	€ million
1	Germany	5 767
2	United Kingdom	5 187
3	Switzerland	4 965
4	France	4 392
5	Belgium	2 343
6	Denmark	1 411
7	Italy	1 230
8	Spain	997
9	Sweden	942
10	Natherlands	642
11	Austria	453
12	Finland	264
13	Poland	227
14	Romania	200
15	Ireland	194
16	Slovenia	164
17	Hungary	158
18	Norway	141
19	Portugal	88
20	Greece	84
21	Turkey	83
22	Czech Republic	49
23	Croatia	40
24	Cyprus	14
	Total	30 035

Source: The Pharmaceutical Industry in Figures, Key Data, 2014,
European Federation of Pharmaceutical Industries and Associations

Clinical trial

- ...trials to evaluate the effectiveness and safety of medications or medical devices by monitoring their effects on a groups of people.



- ...may be conducted by government health agencies, researchers affiliated with a hospital or university medical program, independent researchers, or pharma industry.

Clinical trial sponsors

Source: Clinical Trial Magnifier Vol. 1:10 Oct 2008

www.ClinicalTrialMagnifier.com

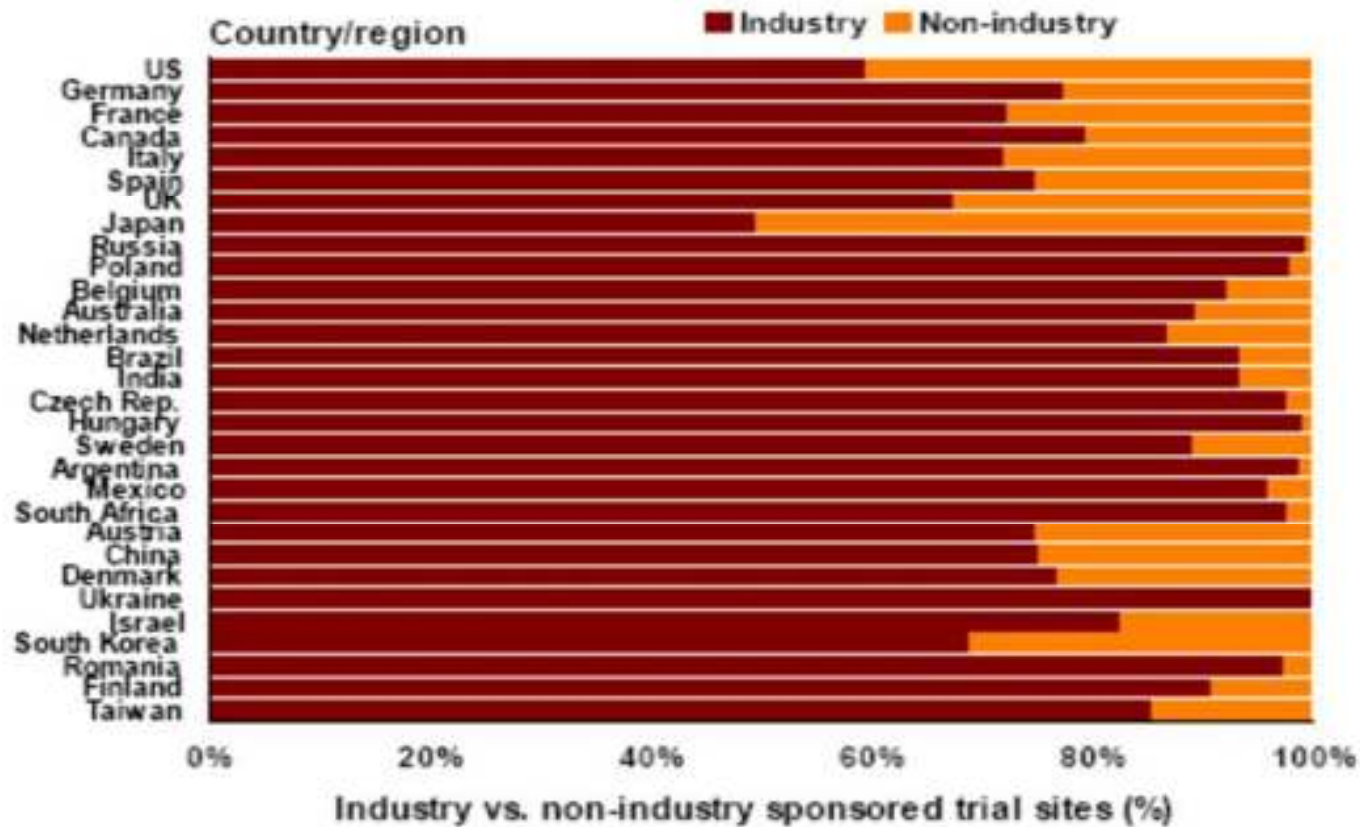


Figure 7. The proportion of industry versus non-industry sponsored phase II-IV trial sites by country/region (values taken from Table 4).

History

- Clinical research on a large scale developed at the beginning of the last century in the US, Canada, Japan and Western Europe.
- Global GCP standards introduced in the industry in 1996 initiated globalization trends in this area. Industry started to search for new markets.
- At the same time political and economic changes meant that Poland became the reliable market for this activity. Joining the EU and adoption of EU Directives governing the conduct of clinical trials facilitated this activity even more.

Clinical trials in Poland



Source:

1. Data for 2003-2009 *Badania kliniczne w Polsce – Główne wyzwania*, PWC, listopad 2010

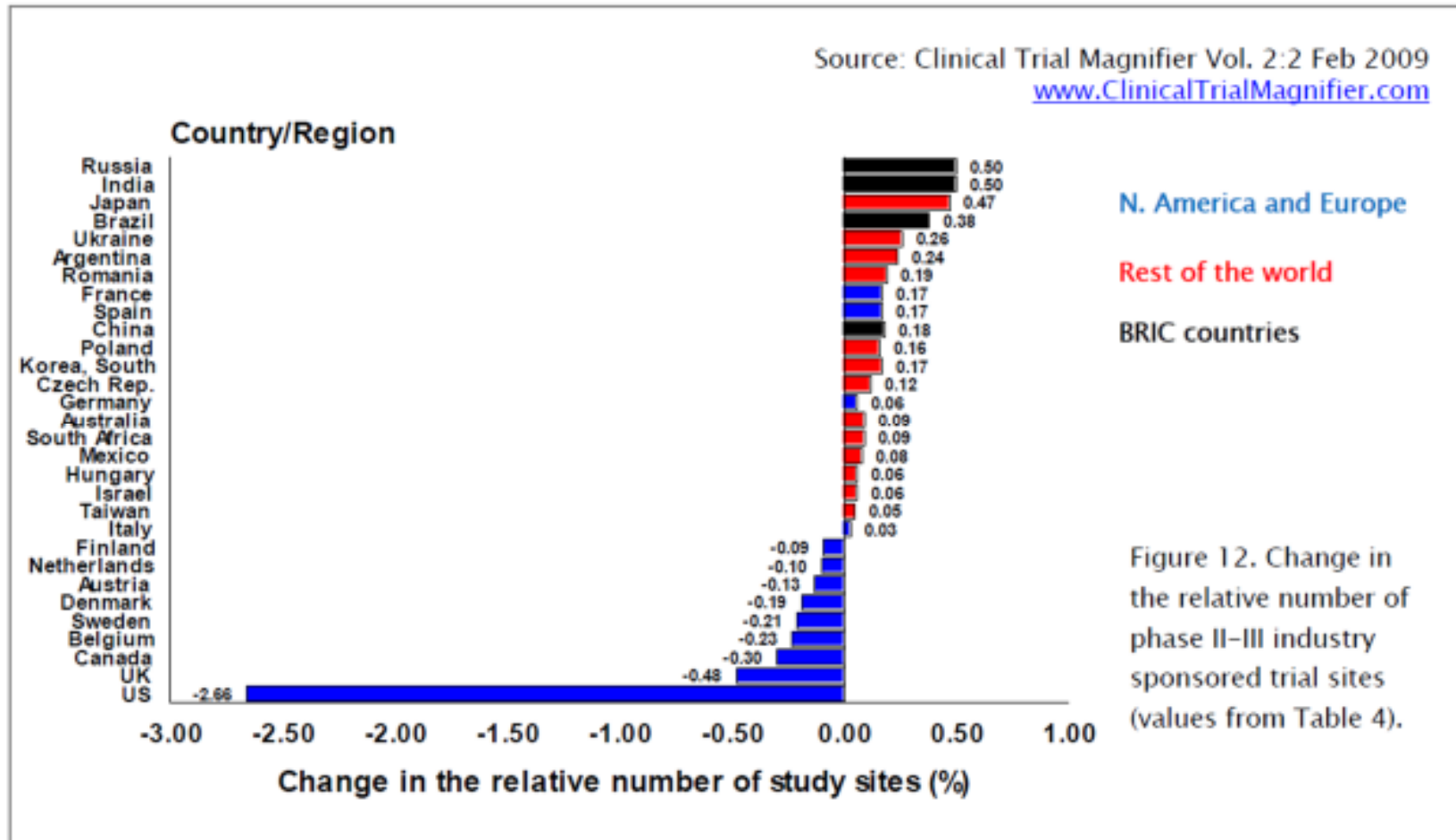
2. Data for 20010-14 Office for registration of medical products, medical devices and biocidal products. Average phase distribution I 10%, II 30%, III 55%, IV 5%)

Investigator sites location

Table 4. The number of industry sponsored phase II-III clinical trial study sites registered with the US trial register for the 60 most active countries for two periods – from 2006.02 for 3 full years and from 2005.10 for two full years. The countries are ranked according the number of industry sponsored phase II-III clinical trial sites.

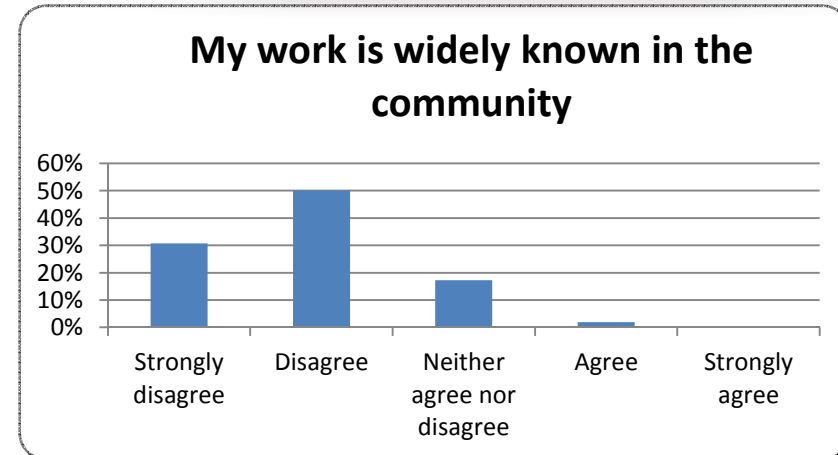
Country / Region	From 2006.01 3 full years		Phase II-III Sites n	%	From 2005.10 2 full years		Phase II-III Sites n	%	Rank Difference	Percentage Difference %
	Rank				Rank					
US	1	67,372	44.4	1	49,257	47.1	0		0	-2.66
Germany	2	9,420	6.2	2	6,438	6.2	0		0	0.06
Canada	3	6,004	4.0	3	4,456	4.3	0		0	-0.30
France	4	5,691	3.8	4	3,746	3.6	0		0	0.17
Japan	5	4,427	2.9	8	2,567	2.5	-3		-3	0.47
Spain	6	4,311	2.8	6	2,792	2.7	0		0	0.17
Italy	7	3,889	2.6	7	2,648	2.5	0		0	0.08
UK	8	3,592	2.4	5	2,976	2.8	3		3	-0.48
Russia	9	3,513	2.3	10	1,904	1.8	-1		-1	0.50
Poland	10	3,245	2.1	9	2,071	2.0	1		1	0.16
Australia	11	2,413	1.6	12	1,573	1.5	-1		-1	0.09
India	12	2,299	1.5	18	1,066	1.0	-6		-6	0.50
Belgium	13	2,048	1.4	11	1,657	1.6	2		2	-0.23
Brazil	14	1,991	1.3	20	972	0.9	-6		-6	0.38
Argentina	15	1,971	1.3	17	1,111	1.1	-2		-2	0.24
Czech Republic	16	1,904	1.3	14	1,206	1.2	2		2	0.12
Netherlands	17	1,823	1.2	13	1,364	1.3	4		4	-0.10
Hungary	18	1,767	1.2	15	1,152	1.1	3		3	0.06
Mexico	19	1,543	1.0	19	981	0.9	0		0	0.08
Ukraine	20	1,533	1.0	23	782	0.7	-3		-3	0.26
South Africa	21	1,401	0.9	21	875	0.8	0		0	0.09
Sweden	22	1,320	0.9	16	1,126	1.1	6		6	-0.21
China	23	1,273	0.8	27	687	0.7	-4		-4	0.18
Israel	24	1,186	0.8	25	759	0.7	-1		-1	0.06
Romania	25	1,165	0.8	31	600	0.6	-6		-6	0.19
Korea, South	26	1,163	0.8	30	628	0.6	-4		-4	0.17
Austria	27	1,018	0.7	22	835	0.8	5		5	-0.11
Denmark	28	838	0.6	24	773	0.7	4		4	-0.19
Finland	29	819	0.5	28	661	0.6	1		1	-0.09
Taiwan	30	818	0.5	32	512	0.5	-2		-2	0.05
Bulgaria	31	783	0.5	36	416	0.4	-5		-5	0.12
Slovakia	32	742	0.5	33	511	0.5	-1		-1	0.00
Greece	33	619	0.4	34	485	0.4	-1		-1	-0.01
Norway	34	582	0.4	29	635	0.6	5		5	-0.22
Switzerland	35	578	0.4	37	413	0.4	-2		-2	-0.01
Turkey	36	523	0.3	40	258	0.2	-4		-4	0.10
Chile	37	507	0.3	38	262	0.3	-1		-1	0.08
Portugal	38	495	0.3	35	427	0.4	3		3	-0.08
Philippines	39	424	0.3	39	261	0.2	0		0	0.03
Peru	40	417	0.3	43	205	0.2	-3		-3	0.08

Trends



Challenges

- ‘Sensitive business’
- Lack of knowledge in society or negative public perception ^{1, 2}



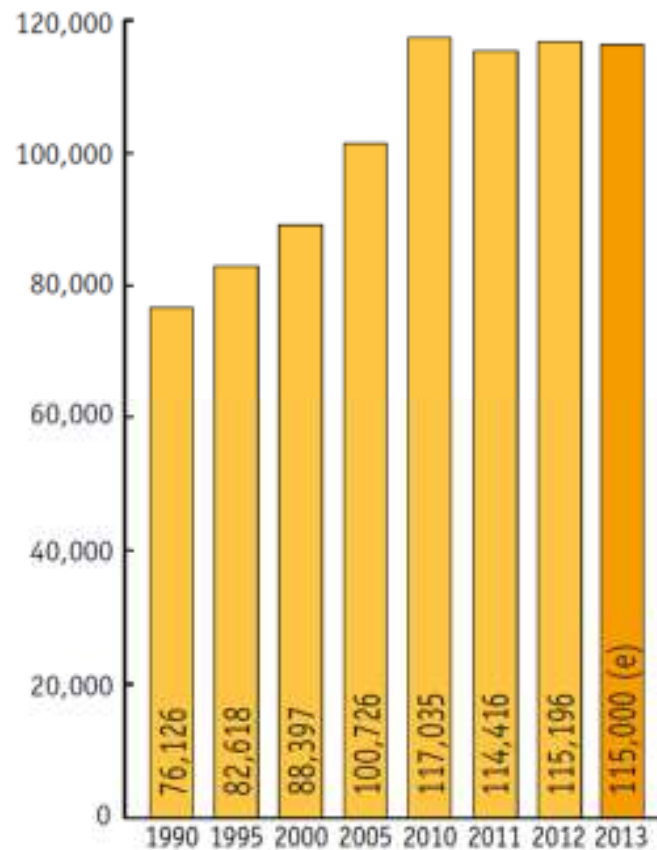
- Audit performed in Poland in 2009 by National Chamber of Control in 13 Teaching Hospitals showed deficiencies in the financial aspect of this business³
- The quality of the research done in this part of Europe was questioned by some scientists from established markets⁴

Sources:

1. GCPpl Assotianions reports, June 2014
2. Own research, a sample of 52 polish employees of pharma research companies and CRO
3. National Chamber of Control, Audit report, December 2010
2. Glickman et al. , Ethical and scientific implications of the globalization of clinical research. New England Journal of Medicine, 2009.

Employment in R&D in Europe

EMPLOYMENT IN PHARMACEUTICAL R&D (1990-2013)



Note: Data includes Bulgaria and Turkey (since 2012), Poland (since 2010), Czech Republic, Estonia and Hungary (since 2009), Romania (since 2005) and Slovenia (since 2004) Croatia, Cyprus, Greece, Latvia, Lithuania, Malta, Serbia, Slovakia: data not available

Source: EFPIA member associations - (e): EFPIA estimate

Source: The Pharmaceutical Industry in Figures, Key Data, 2014, European Federation of Pharmaceutical Industries and Associations

Clinical trials market employees in PL

- In 2010 it was estimated that 1200 Clinical Research Associates work in Poland₁
 - Physicians, pharmacists and other medicine related professions, many on PhD degree
 - Do not regret changing profession
 - Satisfied with the new profession (important, interesting, self-realization)₂

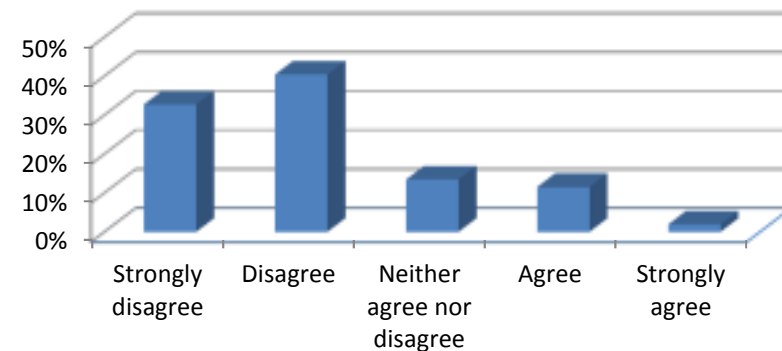
Sources:

1. Badania kliniczne w Polsce – Główne wyzwania, PWC, listopad 2010

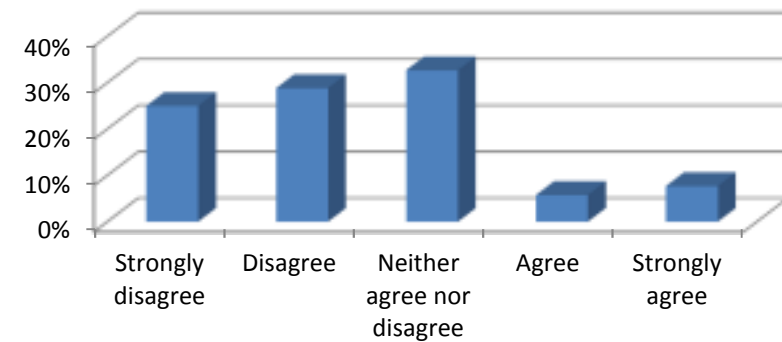
2. Own research, a sample of 52 polish employees of pharma research companies and CRO

Clinical research market employees

I regret that I do not do the profession consistent with my education.

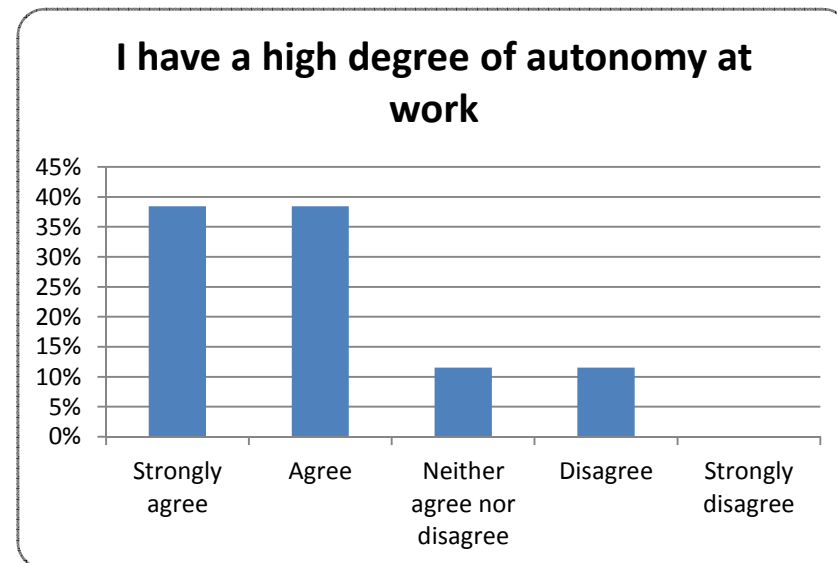
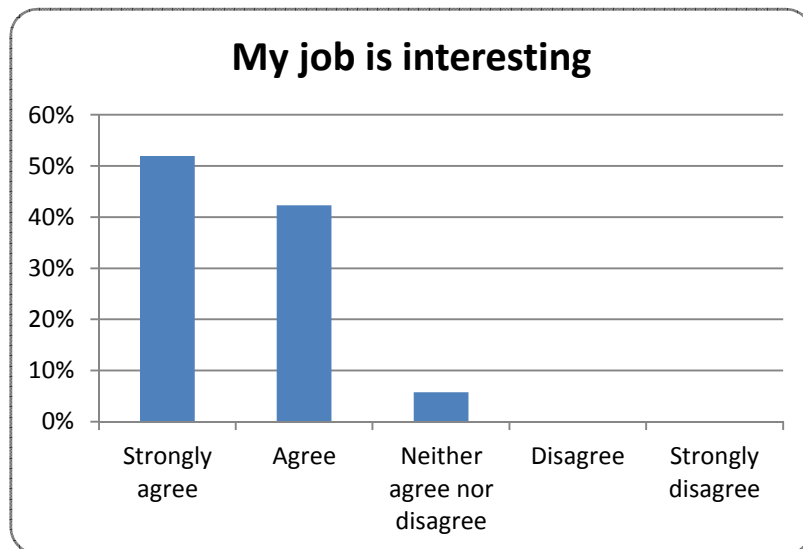
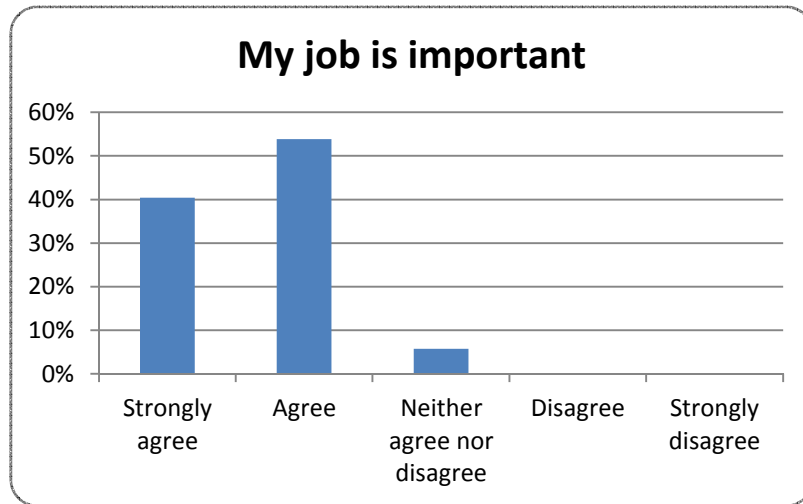


I would be happy to take a very big effort to return to the learned profession: physician, pharmacist, biologist, biotechnologist, ...



Source: Own research, a sample of 52 polish employees of pharma research companies and CRO

Clinical research market employees



Source: Own research, a sample of 52 polish employees of pharma research companies and CRO

Further development in Poland

- The market is still developing and, what is more important new, higher level R&D activities, like central data management or global R&D organizations are being established