

## R&D Offshoring to Emerging Economies: Can Poland compete?

Tomasz Mroczkowski\*

### **Abstract**

Economists have analyzed offshore outsourcing mainly from the perspective of transaction costs and procurement decisions. In the current phase of globalization offshoring practice increasingly involves high value added activities such as design and R&D. Today's globalized R&D system embraces increasingly capable emerging economies that offer firms new options in terms the offshoring not just development but also research functions. However the offshoring of R&D to emerging economies entails higher levels of risk and uncertainty. The literature review shows that problems associated with this kind of R&D offshoring have seen few studies and are not well understood – especially in a comparative perspective of the practices of companies based in different countries with distinctive business philosophies. Some evidence points to differences in the offshoring practices of US companies – as “globalization leaders”– with those of German companies as “reluctant globalizers”. The paper reports the preliminary results of an ongoing study of offshoring of pharmaceutical and biotechnology R&D to emerging economies. In this study we compare clinical trials destinations chosen by US and German companies – using the American government clinical trials database. We find interesting differences which however do not support the hypothesis that German companies are less aggressive about offshoring clinical trials than US based ones. We also look at the position of Poland as a site for offshored R&D and make recommendations about how the country could improve its competitiveness in this domain in the future.

**Keywords:** Innovation, R&D, Offshoring, Germany, Pharmaceutical Industry, Biotech, Poland.

**JEL Code:** F23, O32.

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## **Introduction: emerging economies embrace global R&D**

Offshoring today embraces not just IT and business process (back office) functions but also marketing, engineering, procurement, product development, design and R&D. Just as IT outsourcing is showing signs of maturing, the new trend is global innovation offshoring which is growing at double digit rates and encompasses product development and design as well as R&D (Jaruzelski, Dehoff, and Bordia, 2006). The cited report documented that one third of companies in the Health/Pharmaceutical/Biotech industries were engaged in offshoring R&D and that this practice was expected to continue and grow. A study of British pharmaceutical companies showed that between 1998 and 2003 the percentage of firms engaged in sourcing at least some of their R&D requirements externally grew from 56.6% to 72.4% (Howells, Gagliardi, and Malik, 2012).

In the past, the geographical scope of innovation offshoring used to be largely confined to developed countries. In the 2000s most large emerging economies had decided to pursue national strategies of building knowledge economies (Mroczkowski, 2011).

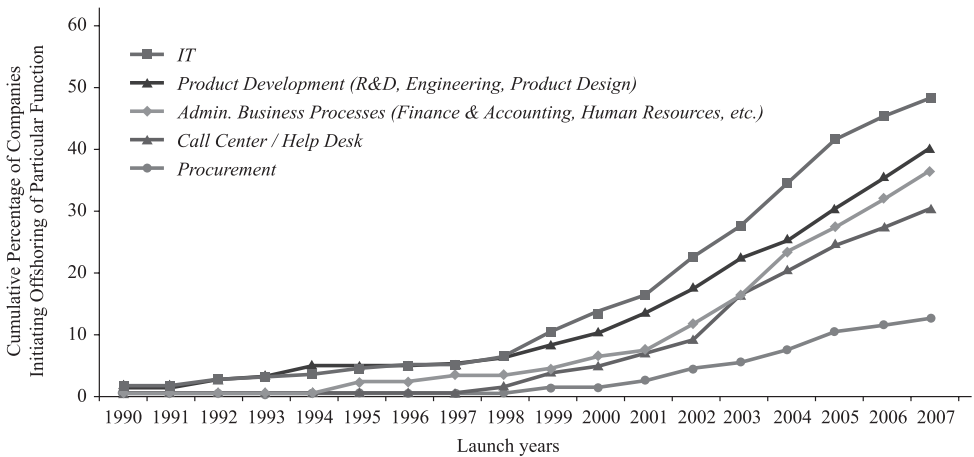
The emergence of a system of global R&D that embraces increasingly capable emerging economies offers pharmaceutical and biotech companies new options in terms of investments, acquisitions and the offshoring of R&D functions with potential new cost advantages offering the possibility of significantly reducing the very high costs of drug development (estimated to be around 1 billion USD at present). While the outsourcing of IT and business processes has been the subject of many studies, R&D offshoring is less well understood (Hatonen and Eriksson, 2009; Mudambi and Tallman, 2010; Martinez-Noya and Garcia-Canal, 2011). The offshoring of R&D is peculiar as it entails higher levels of risk and uncertainty, the problems of prior disclosure and information asymmetry and moral hazard (Doctor, Newton, and Pearson, 2001; Howells et al. 2012; Kim, Beldona, and Contractor, 2007). These peculiarities of R&D offshoring are likely to be amplified when the offshoring destinations are located in emerging economies.

The objective of the present study is to explore this phenomenon in the case of the biotechnology and pharmaceutical companies using a comparative international perspective. Up until now academic surveys of R&D offshoring have used a single country perspective and have not distinguished between offshoring to developed as opposed to emerging economy destinations. We do not know whether different factors drive the propensity of companies to offshore R&D to emerging economies: does the national location of companies play a role in this process or not?

We chose to compare companies from the United States-the global industry leader and also a keen supporter of globalization, with companies based in Germany. Germany remains a major world player in the industry, however for a number of political and cultural reasons discussed in the literature, is often seen as a “reluctant globalizer”. Our study included two phases. The first was a

comparative analysis of clinical trials destinations-chosen by US as compared with German companies. The analysis used the American government clinical trials database. The second phase, based on a detailed company survey, extended the scope of the study to include preclinical as well clinical studies but also discovery research offshoring by pharmaceutical and biotech companies from the two countries. The survey targets R&D managers responsible for Strategic R&D decisions.

In this paper we report the results of the first phase. In particular, we consider to what degree Poland is a destination of outsourced R&D by US and German biopharma companies.



**Figure 1.** Progress of Offshoring Practices by US Companies, 1990 – 2007.  
Source: Manning, Stephan, Massini, Lewin, 2008.

As we mentioned the United States is an obvious choice for studies of biopharma offshoring. America has the largest number of large global pharmaceutical (pharma) companies and also dominates the biotechnology sector. US technology companies are leaders in charting new global strategies such as the aggressive use of offshoring as we document below (Figure 1).

Germany, the birthplace of the modern pharmaceutical industry, continues to be an important player not just in Europe but also globally, but the country has its own distinctive business philosophy that sets it apart from the US. There are signs of declining innovativeness of German pharmaceutical companies. Patent registration in Germany has seen some declines and, according to a study by the EU, in 2005, only 6 of 140 newly approved pharmaceutical drugs were developed in Germany (BBT, 2011).

## 1. Literature review

### 1.1. Studies of International Offshoring Practices

Various reports have pointed out the economic benefits and also the costs of offshoring. Those benefits may not be the same for different countries. The OECD's report on Offshoring and Employment (2007b) lists various benefits of offshoring, detailing in multiple sections how consumer incomes grow, competitiveness and productivity improve, exports grow, national inflation is better controlled, and returns on capital increase. Specifically, the OECD report points out that, according to the McKinsey Global Institute, the United States repatriates \$1.14 for every dollar offshored in the services sector, as opposed to EUR 0.86 and EUR 0.74 for every euro France and Germany offshores, respectively. "Three main reasons explain the differences with the United States," the OECD report explains. "First, the labor cost savings are less in France and Germany because wages in their destination countries are higher than those in the case of the United States... Second, the United States takes greater advantage of the wealth created in the destination countries, and their additional demand, exporting more to those countries. And third, persons who lose their jobs to offshoring in the United States tend to find other work more quickly." The report goes on to explain that despite differences with the United States, Germany and France still benefit significantly from offshoring, and that without offshore outsourcing their costs would be dramatically higher (OECD 2007a, 2007b).

The literature on outsourcing has several strands. Earlier studies consider critically the process in a strategic perspective of cost cutting and 'make or buy' decisions (Domberger, 1999; Quinn, 1999; Grossman and Helpman, 2005; Hatonen and Eriksson, 2009) link outsourcing with organizational transformation and dynamic networking capabilities. Other authors address the impact of offshoring on innovation. For example, Ernst argues that: "By investing in offshore R&D labs, companies are able to substantially reduce the cost of U.S.-based scientists and engineers but also gain access to complementary innovative capabilities. Furthermore, innovation offshoring helps U.S. companies to penetrate the growing and increasingly sophisticated markets of Asia." (2006: 36). Howells et al. point out that outsourcing associated with R&D is different and has its peculiarities: "sourcing knowledge, research and technology inputs externally is different from other outsourcing activities" (2012: 141). The key specificities of managing R&D outsourcing include prior disclosure of information and information asymmetry. Thus in the context of R&D even the supplier of knowledge does not know the final quality of the knowledge, as they themselves do not know a priori the future outcomes of their work (Howells et al. 2012). Carter (1989) states that each exchange of information associated with knowledge and research is essentially a unique event and is therefore not like repeatable transactions. Cavusgil, Calantone, and Zhao (2003) point out that much of the know-how exchanged in the outsourcing process is highly tacit in nature, hence more difficult

to control and administer. A distinctive feature of research outsourcing is the high level of risk and uncertainty (Doctor et al. 2001). Both producers and consumers of research are involved in co-joint production of new knowledge leading to intellectual property rent sharing and moral hazard problems (Howells et al. 2012; Alchian and Demsetz, 1972). The more science intensive the field – and biopharma is perhaps the most science intensive industry of all – the more acute these challenges become and the more risk management must face. The choice of the geographical destination of offshoring adds another dimension of risk and uncertainty.

## 1.2. Offshoring and National Differences

While American companies can be considered pioneers in offshoring, today it has become a global best practice – which does not mean that there are no significant differences among patterns of offshoring performed by companies based in different countries. Scholler (2007) found that German companies were increasing the intensity of their service offshoring activities at a faster rate than American companies between 1991 and 2003. The same author found that German firms had, during the timeframe of the study, tended to offshore a larger percentage of material production than US companies. The study however did not compare innovation related offshoring.

Other comparative studies have focused on differences in choosing offshore locations, factors that drive the choices and what these choices reveal about managerial attitudes. In their study reporting on the 2006 Offshoring Research Network Survey, Lewin and Couto (2007) conclude that Germans favor European locations while American firms favor India and China.

As regards direct comparisons of innovation offshoring practices, several reports suggest that in this area German firms may either be lagging or following their own distinctive practices. According to the OECD's "Science, Technology, and Industry Scoreboard" for 2011, 11.4% of German innovative firms engaged in collaboration with other firms within Germany between 2006 and 2008, and only 8.3% collaborated with firms internationally during the same period. Among OECD countries, eighteen nations have at least double the percentage of international collaborations than Germany when compared to all OECD countries analyzed with respect to innovation collaboration. For instance, among UK firms, 37.3% partnered with national firms and 32.2% with international firms. In addition, most international collaboration by German firms remains solely in Europe. Comparing these numbers to previous years shows that German firms are increasing foreign collaboration practices, though much more slowly than the vast majority of OECD nations. In terms of percentages of innovative firms engaged in just intra-European collaboration Germany, in spite of progress, continues to rank near the bottom in 14th place ahead only of Italy and Spain (OECD, 2007a, 2011). So even within Europe itself German companies have a lower propensity

for international collaboration. This appears to also be reflected in Germany's under-performance in receiving business R&D (BERD) from abroad. According to the 2011 OECD report, R&D funding from abroad amounted to an average of 10.33% of total business expenditures on research and development (BERD) in 2008.

Germany's percentage of BERD from abroad was well below the average, amounting to only 3.71% the same year- compared to 21.65% in the UK and 10.36% in France (OECD, 2011). With over 20 countries well ahead of Germany in receiving R&D funds from abroad, German innovation may be affected. A recent German government commission report on innovation appears to recognize the problem: "Within the High-Tech Strategy 2020, efforts to forge effective links between foreign policy, innovation policy and business development should be intensified. Internationally, Germany still has too little presence with new forms of international innovation and knowledge transfer. The international component of Germany's innovation policy seems rather weak even in comparison to the corresponding policy components of smaller European countries such as Switzerland, Sweden, Finland, Austria and Denmark. The Expert Commission proposes that this discrepancy be promptly eliminated and that bridge-building organizations be established, at leading innovation centres, to carry out and combine tasks in the areas of a) international science policy and b) promotion of innovative German companies with a view to greater international market presence." (EFI, 2011: 42).

### **1.3. Studies Focused Specifically on Offshoring in Biotech and Pharmaceuticals**

The biotech and pharmaceutical industries rely perhaps more than any others on innovation and are of critical importance to both Germany the US and other developed countries. This industry has also experienced a rapid rise in offshoring. In 2006, the US pharmaceutical industry employed approximately 1.97 million persons (FTEs), of which over 300,000 were in R&D. Sixty to sixty-five thousand persons worked in clinical support functions, and at present, it is estimated that only about 10% are "globalized" or "offshored". However, it is estimated that this ratio is likely to reach 30% and could, in theory, be as high as two-thirds of FTEs (McKinsey & Company, 2008).

In the pharmaceutical and biotechnology industries, the "strategic and integrated" approach to innovation and R&D has seen a growth since the 1990s with a huge expansion of external innovation partnerships with biotechnology companies and specialized providers of genomics research, bioinformatics, combinatorial chemistry or high throughput screening. In her 2004 book "Outsourcing R&D in the Pharmaceutical Industry," Bianca Piachaud lists 25 specialist providers of genomic research; all the firms listed are from the USA. Similarly most providers of combinatorial chemistry expertise and services until a few years



ago were American or West European firms. For example a list of academic research partnerships in six therapeutic areas funded by the then-GlaxoWellcome company had six universities or research Institute from the USA, four from the UK and one each from Sweden and Australia (Piachaud, 2004). A similar focus on developed world companies can be seen in the list of contract research organizations (CROs) with clinical development expertise that is included in the cited publication.

Different pharma companies have shown different levels of commitment to the process by outsourcing different amounts of chemistry work, data management, biometrics or discovery. For example two American companies Eli Lilly and Merck are considered leaders in moving to strategies based on network based innovation – which includes aggressive R&D offshoring to emerging economies like India and China (Mroczkowski, 2011). Wyeth is considered a leader in globalizing end-to-end clinical data management. After its 2003 decision to offshore the complete data management function to Accenture, Wyeth transferred 100 full-time jobs to Accenture with much larger increases of globalized jobs engaged in clinical data management for Wyeth and with cost reductions that could exceed 40%.

There are relatively few academic studies of R&D offshoring and outsourcing specifically in the pharmaceutical industry-especially ones that are up to date. (Howells, Gagliardi, and Malik, 2008). One such study by Howells et al. (2012) is notable. It reports the results of a recent survey of R&D outsourcing in UK pharmaceuticals. The authors set out to explore what factors drive the propensity to outsource R&D at the business unit level. Research questions include: what are the relationships between the likelihood of outsourcing R&D and the R&D intensity of the firm as measured by share of R&D budget, the average labor intensity of projects and the business unit size.

The authors find that there is no relationship between the size of the business and the likelihood to outsource. However the share of the total R&D budget outsourced is positively and significantly associated with the R&D intensity of the business. The authors interpret this finding as indicating that for firms to be effective in outsourcing R&D requires them having significant absorptive R&D capacity by possessing internal R&D capabilities – suggesting that undertaking in-house R&D remains complementary to, rather than a substitute for outsourcing R&D (Howells et al., 2012). The authors acknowledge that this finding is not consistent with a study of 86 US pharmaceuticals (Sen, 2009). The UK survey found support for the idea that businesses undertaking more labor intensive R&D operations and which in turn are more likely to be associated with more basic, fundamental research activities, will intend to undertake this work in-house. By contrast, more capital intensive and routine activities likely to benefit from scale effects were more liable to be outsourced. As regards “project density” (PD) the study found that the lower the PD and so the larger the size of the projects, the lower was the likelihood of outsourcing a larger share of the R&D budget. (Pro-

ject density was defined as the average size of projects – measured by the number of projects per numbers of full time equivalent R&D employee [Howells et al, 2012]) The authors interpret this finding to suggest that the greater the knowledge resource capacity available to firms with lower project density, the more R&D “slack” is available to the business. Larger more complex and uncertain research requirements tend to preclude market-based contracts. *In other words, forms of R&D which are more routine in nature and have low levels of uncertainty and complexity lead to a preference for “arms length” arrangements are more likely to be outsourced* (Howells et al., 2008). As the authors acknowledge, this interesting study has limitations. It is “British-centric” and great caution should be taken when generalizing the findings. The study does not look at the destinations of the outsourced work – in particular at R&D offshoring to emerging economies. It uses the term pharmaceutical R&D without specifically distinguishing between pre clinical, clinical trials and discovery research.

## 2. The study and its research questions

The present study aims to focus very specifically on the offshoring of both pharmaceutical and biotechnology R&D to emerging economies by looking separately at pre-clinical research, clinical trials and discovery research. We adopt an explicit comparative perspective as we survey US based and German based pharma and biotech companies.

As the cost pressures and the consequences of the “patent cliff” have impacted pharma and biotech companies, they have been forced to respond by drastically revising their R&D strategies and moving to a model of open global innovation. Our study not only aims to capture these most recent trends in R&D offshoring but also to offer a forecast by asking managers to predict most likely company practices in 5 and 10 years time. We explore the role of the national base in offshoring decisions and aim at providing an understanding of factors that shape managerial decision to offshore to the more risky destinations of emerging economies. Our key research questions for the study are:

1. To what extent pharmaceutical and biotech companies based in the US and in Germany offshore not just pre-clinical and clinical trials but also discovery research to emerging economies? Do they plan to extend those practices in the next 5-10 years?
2. Are there significant differences in the offshoring practices of German companies as compared to those of their US based counterparts?
3. What are the similarities/differences in terms of the reasons why companies from the two countries offshore discovery research as compared with reasons for offshoring pre-clinical and clinical trials? Why do some companies refrain from offshoring to emerging economies?
4. What are the key risks management associates with the different types of offshoring?



5. To what degree are the results of offshoring to emerging economies meeting management expectations? Do companies have plans to bring back some activities to the home country (backshoring) and what would be required to encourage them to do so?
6. What is the role of Poland as a destination for offshored biopharma R&D.

### **2.1. Research Design and Methodology: Phase 1 and Phase 2 of the Study**

In order to find answers to the broad research questions we first performed a preliminary study (phase 1) of the destinations of clinical trials performed by large and medium sized pharmaceutical companies from the US and Germany. Such information is publicly available from the US government database of clinical trials (ClinicalTrial.gov), which are listed by company and country where the trials took place. Using this database we were able to describe in detail the distributions of clinical trials destinations chosen by companies from the two countries. Using the criterion of GDP per capita and geography we categorized the destinations into the following groups: domestic trials, trials offshored to developed economies, trials offshored to emerging economies and trials “nearshored” to neighboring countries. Results of research of the database are presented in the “Results of Phase 1” section of the paper below.

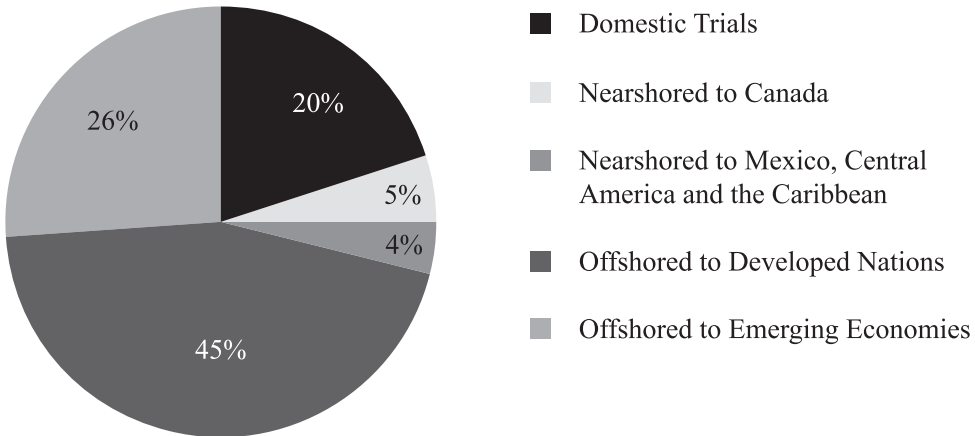
The second phase of the study began in 2012 and is still under way. It is based on a survey of top R&D managers of German and US pharmaceutical and biotech companies and asks specifically about the offshoring to emerging economies of the three components of biopharmaceutical R&D: pre-clinical studies, clinical trials and discovery research.

According to the 2011 report “The German Pharmaceutical Industry” (Germany Trade and Invest 2011) the 243 companies comprising this sector generated a turnover of 41.5 billion euros of which 24.1 billion came from exports, making Germany the fourth largest producer in the world. German companies are organized into several associations. The biotech companies are in BioDeutschland while the pharmas are organized in two associations of which the VFA (Verband forschender Arzneimittelhersteller) groups the pharmaceutical companies that perform significant research.

By the Fall of 2013 we expect to have at least partial US results allowing us to make some comparisons with the German results. As the questionnaire used in Germany is in English we plan to use it with minor modifications also for gathering data from US based companies. As the population of US biotech and pharma companies is much larger than that of Germany we have designed the US database to be as comparable as possible to the German population of companies in terms of company size, mix of pharmaceutical and biotech firms etc.

### 3. Results Of The Preliminary Study (Phase 1) – Clinical Trials Offshoring: German And US Companies Compared

Using the US government database of clinical trials performed around the world by company, we were able to compare firms based in Germany and the United States (ClinicalTrials.gov).



**Figure 2.** Sourcing of All Clinical Trials of Top 10 Companies in the US.  
Source: clinicaltrials.gov.

On the list of all companies with over 1000 employees, we ranked the companies by number of employees and selected the 10 largest companies headquartered in the US and Germany<sup>1</sup>.

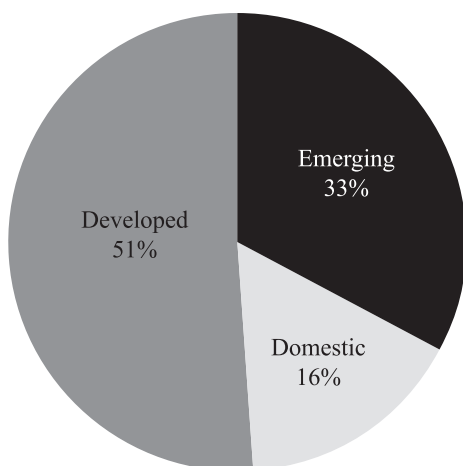
Figures 2 and 3 reflect the distribution of location of all clinical trials performed by this sample of companies. The nearshoring regions are those specified in the figure. In terms of offshoring, by “developed nations” we mean those countries with GDP over 20,000 USD whereas “emerging economies” are those countries with GDP less than 20,000 USD.

In Figure 2 we find the results for the U.S. showing that American based companies actually conduct relatively more clinical trials domestically (20%) than do comparable German firms (8%).

<sup>1</sup>Data was obtained from clinicaltrials.gov. In the U.S., the top ten companies ranked were Procter and Gamble, Johnson & Johnson Pharmaceutical, Pfizer, Merck, Abbott Laboratories, 3M, Baxter Healthcare Corporation, Eli Lilly and Company, Bristol-Myers Squibb, and Amgen. In Germany, the top ten companies ranked were Fresenius Biotech GmbH, Bayer, Boehringer Ingelheim, B. Braun Melsungen, Merck KGaA, Bayer Schering Pharma, Sandoz, ALTANA Pharma, Grünenthal GmbH, and Merz Pharmaceuticals GmbH.

29% of US trials are conducted either domestically or nearshored to countries within North America and the Caribbean while 71% of trials are sent abroad with a significant slice (26%), being offshored to emerging economies.

Which specific emerging economies were most favored by the leading US pharmaceutical companies? We looked at the ten most popular national destinations (as counted by the actual number of trials performed from 2000-2013) by the top five largest American pharma companies. The results are presented in Figure 2a. What emerges is that Poland is the lead destination in the group of emerging economies with a 16% share of trials ahead of Mexico (12%) and the Russian Federation (11%) and also ahead of India (8%) and China 7%). The prominence

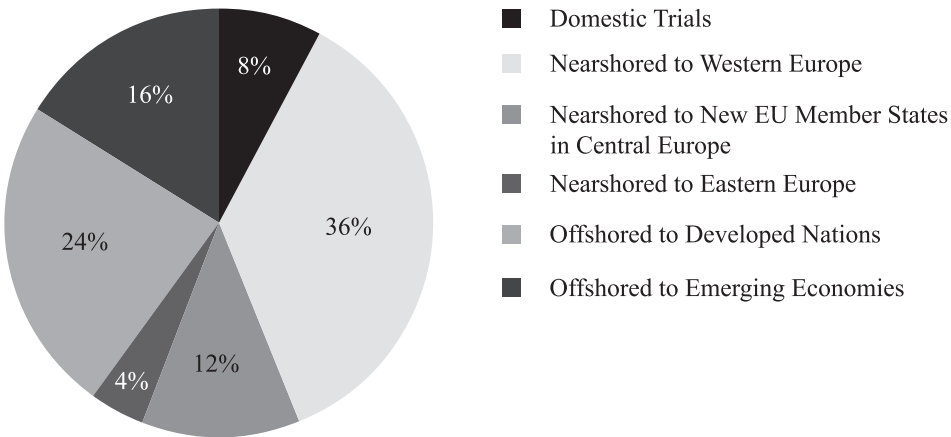


**Figure 2a.** Total Clinical Trial Destinations of Top 5 U.S. Pharma Companies.  
Source: [clinicaltrials.gov](http://clinicaltrials.gov).

of Central Europe is evident with Poland, Hungary and the Czech Republic all new EU member states accounting for a large 36% share! The results for the German companies are presented in Figures 3 and 3a.

Figure 3 shows that the large German pharma companies appear to be very aggressive in their outsourcing of clinical trials, albeit the vast bulk of destinations are in Western Europe (36%) and in the new EU member states of Central Europe (12%), as well as to non European developed nations (24%). Having the less expensive Central European countries nearby – all within the EU economic regulatory space–perhaps unsurprisingly German companies offshore less to non European emerging economies.

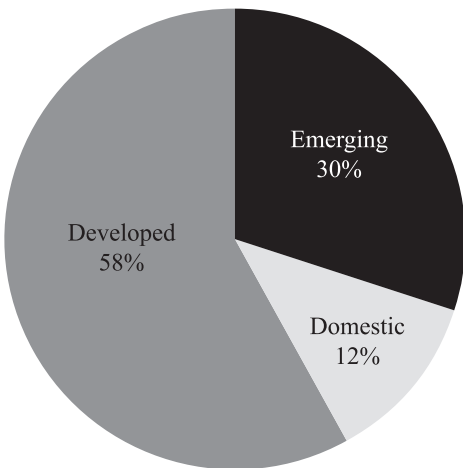
Again as in the case of American firms, we looked at the ten most popular national destinations (as counted by the actual number of trials performed from 2000-2013) by the top five largest German pharma companies. The results are presented in Figure 3a.



**Figure 3.** Sourcing of All Clinical Trials of Top 10 Companies in Germany.

Source: clinicaltrials.gov.

Note: For nearshoring, countries included in the category “Western Europe” are Austria, Belgium, Czech Republic, Denmark, Finland, France, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom. The countries in the “Central Europe” category are Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Estonia, Greece, Hungary, Latvia, Lithuania, Macedonia, Poland, Romania, Serbia, and Slovenia. The countries in the “Eastern Europe” category are Belarus, Georgia, Kazakhstan, Kyrgyzstan, the Republic of Moldova, Russian Federation, and Ukraine. In terms of offshoring, by “developed nations” we mean those countries outside of Europe with GDP over 20,000 USD whereas “emerging economies” are those countries outside of Europe with less than 20,000 USD in GDP.



**Figure 3a.** Total Clinical Trial Destinations of Top 5 German Companies.

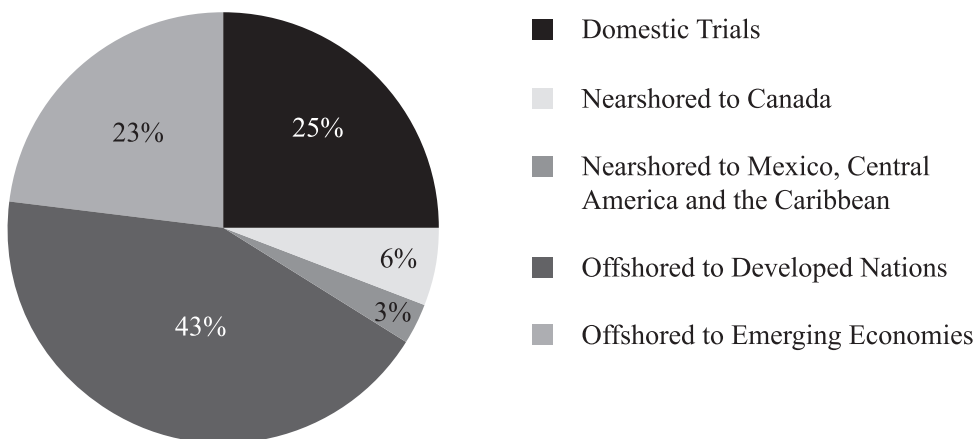
Source: clinicaltrials.gov.

Note: This pie chart depicts the top destinations of German pharma company trials, divided into developed countries, emerging markets and domestic (Germany). The data is based on all clinical trial destinations of the top five companies selected, i.e. Grünenthal, Bayer, Boehringer Ingelheim, Merz KGaA and Merck.

Again among the emerging economy destinations Poland is number one(14%) followed by the Russian Federation(13%). Again the three new member states of the EU: Poland, Hungary and the Czech Republic together account for 35% of the total. If you add Russia and the Ukraine then European emerging economy destinations account for 51% of trials. In fact the distribution of trials to specific emerging economies by German firms is not dissimilar to what the largest American firms do.

Since the number of clinical trials per company ranges from 50 to over 7,000 in the US sample and from 32 to over 3,000 in the German sample (German companies tend to be smaller), we also looked at the “average” behavior of the ten lead companies rather than looking at all clinical trials performed. To represent this “average” behavior of the ten companies, while preventing one company from dominating the sample due to differences in the number of trials between companies, figures 4 and 5 below reflect the mean percentage of clinical trials in each category for the ten firms.

The numbers of mean percentages of trials performed by all ten lead companies in each country confirm most of the patterns found previously. The difference that appears is the larger share of domestic trials in the German case - jumping from 8 to 15%. Clearly US-based firms favor offshoring while German firms prefer “nearshoring”. While American companies on average keep one fourth of all clinical trials at home, compared to just 15% among German companies, when conducting trials abroad American-based firms favor offshoring over nearshoring by more than seven times. German firms, on the other hand, tend to

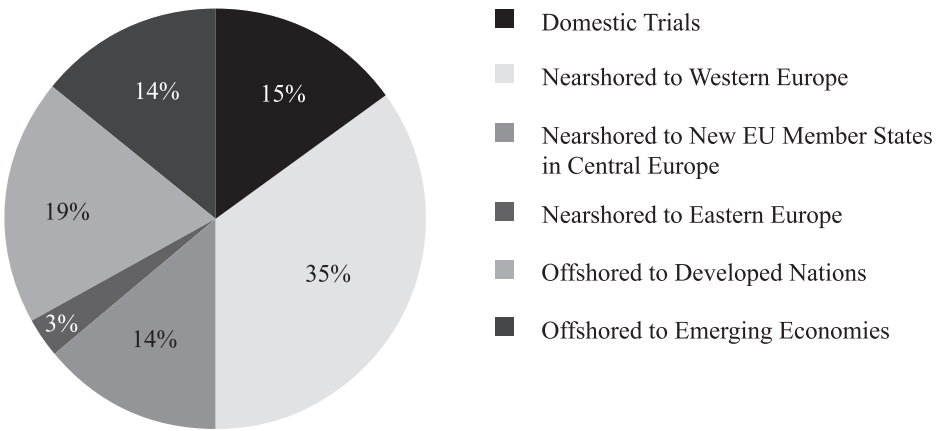


**Figure 4.** Average Sourcing of Clinical Trials of Top 10 Companies in the US.

Source: [clinicaltrials.gov](http://clinicaltrials.gov).

Note: Countries in each of the categories in this table are the same as those in Figure 2.

favor nearshoring over offshoring, keeping 52% of all clinical trials in Europe and sending 33% of trials offshore.

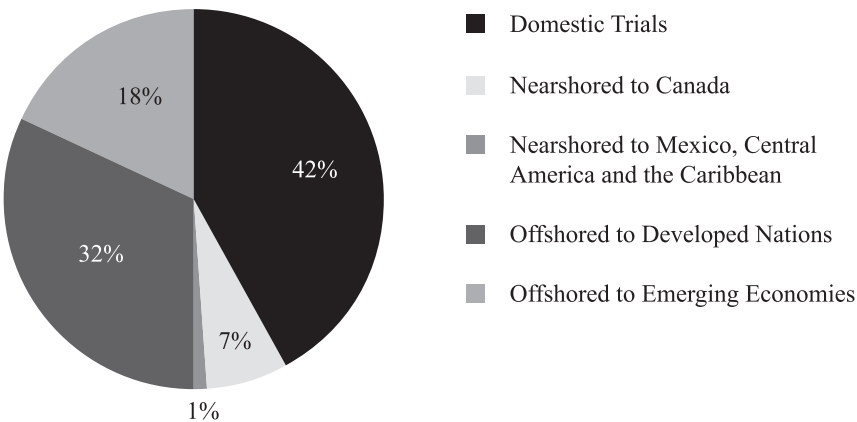


**Figure 5.** Average Sourcing of Clinical Trials of Top 10 Companies in Germany.

Source: clinicaltrials.gov.

Note: Countries in each of the categories in this table are the same as those in Figure 3.

Does the size of companies matter? To answer this question, we also compared data for Small & Medium Pharma Enterprises (SMEs) in both Germany and the US. We defined a pharmaceutical SME as a company employing between 50 and 500 persons.<sup>ii</sup> Figures 6 and 7 below reflect the distribution of location of all clinical trials performed by this sample of companies.



**Figure 6.** Sourcing of All Clinical Trials from Random Sample of SMEs in the US.

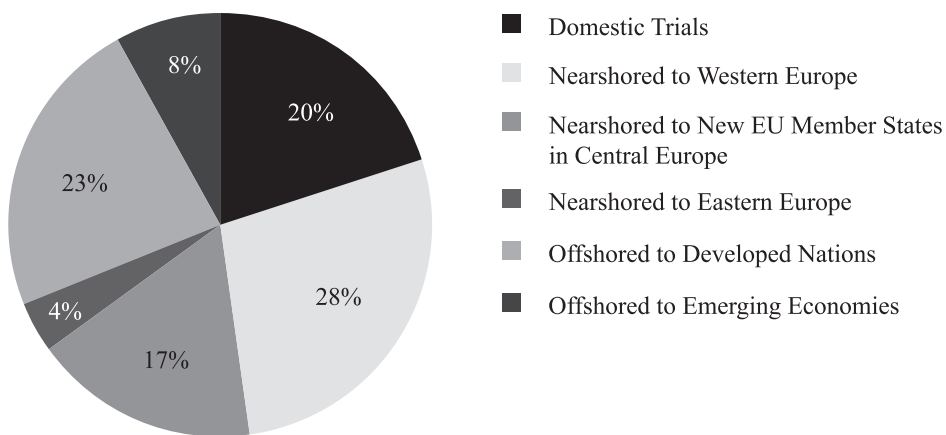
Source: clinicaltrials.gov.

Note: The regional categories used in comparing SMEs is the same as those used for large corporations.



The results confirm that company size does matter: in both the US and Germany, pharmaceutical SMEs conduct significantly higher percentages of clinical trials domestically especially so in the case of the American companies. If we compare the results of large corporations to SMEs in the US, we find that the SMEs are more likely to have an even distribution between domestic nearshored trials and offshored trials. As Figure 6 shows, pharmaceutical SMEs conduct 50% of trials either domestically or nearshored, and the remaining 50% of trials are sent abroad. Though the increase in keeping trials closer to home among SMEs (compared with large corporations) is not as high among German SMEs, still percentages of domestic and nearshored trials remain higher in the German case as compared with the US. As Figure 7 shows, German SMEs perform 65% of their clinical trials either domestically or nearshored to other European countries, while the remaining of trials are offshored outside Europe. As with large corporations, when comparing SMEs in Germany and the United States, we find that Americans are still more likely to offshore their clinical trials abroad.

As in the case of the lead large corporations, we also analyzed the “average” behavior of our sample of pharma SMEs, so as to prevent the data of one company from dominating the sample due to differences in the number of trials

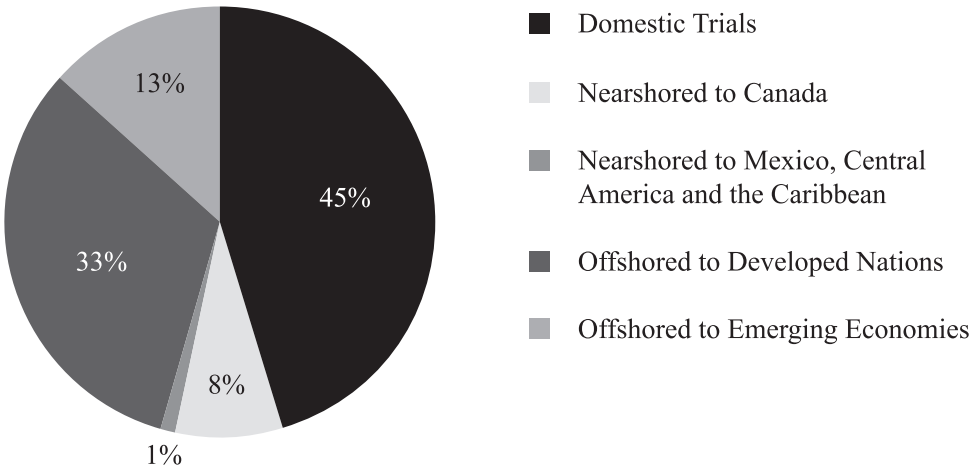


**Figure 7.** Sourcing of All Clinical Trials from Random Sample of SMEs in Germany. Source: [clinicaltrials.gov](http://clinicaltrials.gov).

Note: For nearshoring, countries included in the category “Western Europe” are Austria, Belgium, Czech Republic, Denmark, Finland, France, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom. The countries in the “Central Europe” category are Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Estonia, Greece, Hungary, Latvia, Lithuania, Macedonia, Poland, Romania, Serbia, and Slovenia. The countries in the “Eastern Europe” category are Belarus, Georgia, Kazakhstan, Kyrgyzstan, the Republic of Moldova, Russian Federation, and Ukraine. In terms of offshoring, by “developed nations” we mean those countries outside of Europe with GDP over 20,000 USD whereas “emerging economies” are those countries outside of Europe with less than 20,000 USD in GDP.

between companies. Figures 8 and 9 below reflect the mean percentage of clinical trials in each category for our sample of SMEs.

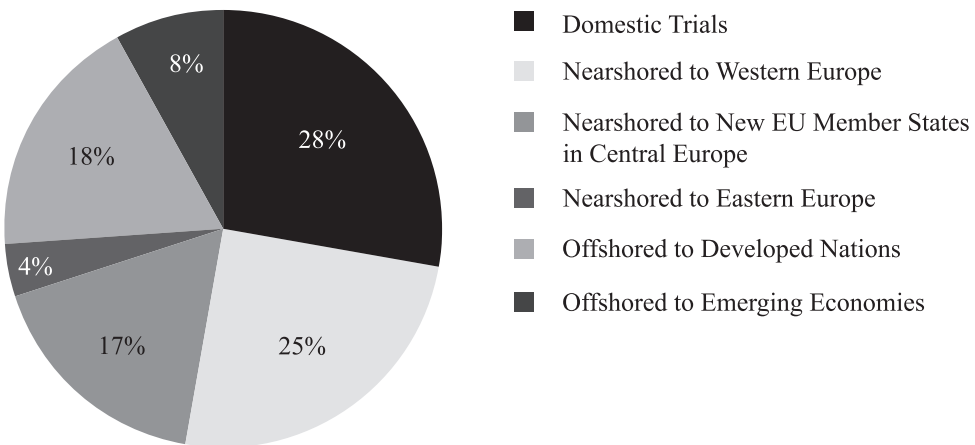
The mean percentages of trials performed within the random sample in each country confirm again that US-based firms favor offshoring while German firms prefer nearshoring. While American companies maintain a higher percentage of clinical trials conducted domestically, 46% of trials are offshored from the US compared to 26% offshored from Germany.



**Figure 8.** Average Sourcing of Clinical Trials from Random Sample of SMEs in the US.

Source: clinicaltrials.gov.

Note: Countries in each of the categories in this table are the same as those in Figure 7.



**Figure 9.** Average Sourcing of Clinical Trials from Random Sample of SMEs in Germany

Source: clinicaltrials.gov.

When comparing the average behavior of the top ten companies in each country to the average behavior of the random sample of SMEs, we find that large corporations and SMEs follow a similar pattern in each country. Large corporations and SMEs in both nations still conduct the majority of their trials in developed nations rather than emerging economies, whether nearshoring or offshoring. However the proportion of clinical trials offshored to emerging economies is quite significant. (If you look at the total population of clinical trials in the entire database [clinical trials.gov]: 33% were performed in the US, 5% in Germany, 42% in other developed economies and 20% in emerging economies)

Our results do not seem to support the view that German companies have a stronger preference for conducting clinical trials domestically- that is within the country. If we add up the proportion of trials offshored to emerging economies with those “nearshored” to the new states of the EU in Central Europe, we find that large German companies are just as aggressive about emerging economy (EE) offshoring as are their American counterparts. The difference is that operating within the single market of the EU they can comfortably target the cheaper new EU member states of Central Europe without assuming the risks of time zone and cultural differences associated with offshoring to places say like India or China. Company size matters as smaller companies tend to conduct more trials domestically and in this case it is the American companies that do so even more than German ones.

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## **Frame 1. Poland as a knowledge based economy**

Poland is currently a “Modest Innovator” according to the European Commission—the lowest performance group among the EU27. Overall R&D investment has been increasing, but remains relatively low relative to GDP. R&D activity is concentrated in lower-value manufacturing. International cooperation is strong in co-patenting, but relatively weak in co-authorship. Internationally funded R&D has increased in recent years.

EU Summary Innovation Index (out of 1): 0.27 (2012)

(rank: 24 out of 27; +0.45% since 2008<sup>[1]</sup>).

Global Innovation Index (out of 100): 40.2 (2012)

(rank: 44 out of 141<sup>[2]</sup>).

### *Domestic Innovation Investment*

Gross Expenditure on R&D [GERD] (as % GDP): 0.75% (2013)

(rank: 28 out of 40; +12% 2005-2013<sup>[3]</sup>, <sup>[4]</sup>).

Publicly-Financed GERD (as % GDP): 0.47% (2010)

(+11.3% since 2005<sup>[3]</sup>).

Business Expenditure on R&D (BERD) (as % GDP): 0.23% (2010)  
(18% of EU average; 20.5% of OECD average, bottom 5; +7.8% since  
2005<sup>[1], [3]</sup>).

**Table 1.** BERD by Sector as percentage of total BERD (2009 vs. 2005)

	High-tech manufacturing	Medium to low-tech manufacturing	High-know- ledge market services	Low-know- ledge services
2009	14.7	51.3	16.7	13.6
OECD median	27.7	33.7	26.6	2.9
2005	18.7	44.0	10.8	14.9
OECD median	31.7	35.0	23.3	3.2

Source: OECD. (2012) "Science and Innovation – Poland." OECD Science, Technol-  
ogy, and Industry Outlook 2012.

<http://www.oecd.org/poland/sti-outlook-2012-poland.pdf>.

### *Internationalization*

**Table 2.** Foreign vs. domestic BERD as percentage of total (2009 vs. 2005)

	Foreign Affiliates	Domestic Firms
2009	50.5	49.5
OECD median	32.6	67.4
2005	30.4	69.6
OECD median	31.5	68.5

Source: OECD. (2012) "Science and Innovation – Poland." OECD Science, Technol-  
ogy, and Industry Outlook 2012.

<http://www.oecd.org/poland/sti-outlook-2012-poland.pdf>.

Major International R&D Investments: General Electric (Engineering Center – Warsaw); IBM (Innovation Centers – Krakow, Lodz, Warsaw, and Bielsko-Biala); Microsoft (Innovation Center – Poznan); Bosh Siemens (R&D Center – Lodz); Unilever (Global Development Center – Poznan); Symantec (Research Laboratory – Warsaw)<sup>[7]</sup>.

International Co-publications: 213 (2011)

(71% of EU average; + 4% since 2007<sup>[1]</sup>).

International Co-patenting as % total patents: 34.6% (2009)

(149% of OECD average; + 9.1% from 1999<sup>[3], [6]</sup>).

*Innovation Outputs*

Triadic Patent Families (per billion \$ of GDP): 0.03 (2010)

(7.1% of OECD average, Bottom 5<sup>[3]</sup>)

SMEs Introducing Product/Process Innovations (as % total SMEs): 14.36%

(2010) (-8.9% since 2006<sup>[1]</sup>)

High-Tech Exports (total value): €8.463 billion (2012)

(rank: 13 in EU27; +172% since 2007<sup>[8]</sup>)

High-Tech Exports (as % total exports): 5.9% (2012)

(rank: 22 in EU27; +97% since 2007<sup>[8]</sup>)

INSEAD/WIPO Key Weaknesses<sup>[2]</sup> Percentile

Innovation Linkages	10.7
Share of patents with foreign inventor	12.8
Microfinance gross loan portfolio	13.1
Creative Intangibles	14.0
Market access for non-aggro exports	16.4
ICT and organizational model creation	17.4
State of cluster development	19.6
New business density	20.0
Tertiary inbound mobility	28.9
Graduates in science and engineering	30.7
Business Environment	31.6
Ease of paying taxes	31.6
GMAT test takers	31.6

*Sources:*

[1] European Commission. (2013) Innovation Union Scorecard 2013.

[http://ec.europa.eu/enterprise/policies/innovation/facts-figures-analysis/innovation-scoreboard/index\\_en.htm](http://ec.europa.eu/enterprise/policies/innovation/facts-figures-analysis/innovation-scoreboard/index_en.htm).

[2] INSEAD and WIPO. (2012) Global Innovation Index 2012.

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[5] Dachs, Bernhard et al. (2012) Internationalisation of business investment in R&D and analysis of their economic impact. European Commission contract report. [http://ec.europa.eu/research/innovation-union/pdf/internationalisation\\_business-rd\\_final-report.pdf](http://ec.europa.eu/research/innovation-union/pdf/internationalisation_business-rd_final-report.pdf).

[6] OECD. (2013) “International co-operation in patents.” OECD.StatExtracts. [http://stats.oecd.org/Index.aspx?DataSetCode=PATS\\_COOP](http://stats.oecd.org/Index.aspx?DataSetCode=PATS_COOP).

[7] Polish Information and Foreign Investment Agency. (2010) The R&D Sector in Poland. [http://www.paiz.gov.pl/files/?id\\_plik=14303](http://www.paiz.gov.pl/files/?id_plik=14303).

[8] EUROSTAT data. (2013) <http://epp.eurostat.ec.europa.eu>.

## **Conclusion: A role for Poland in the global R&D system needs to be enhanced on the research side of R&D**

Our data has show that large German pharmaceutical companies, contrary to expectations in the literature, are actually as aggressive as their American counterparts in conducting clinical trials outside their home country. The key difference is that Germans appear to prefer “nearshoring” to offshoring, moving activities to fellow EU member countries rather than to more distant economies. Due to its proximity, Poland is potentially in a position to take advantage of this dynamic, and is to-date the number one destination for the largest companies from the USA as well as Germany.. This suggests that beyond merely taking advantage of its position as an emerging economy within the EU, Poland is developing a specialization in this kind of activity.

The data profile above suggests that Poland’s internal R&D infrastructure still lags behind its European peers. As we have seen, however, it actually has a relatively strong position as a destination of clinical trials (and to a lesser extent for engineering), though having so far not attracted significant international investments in bio-pharma discovery. It has attracted some international R&D investments in the IT sector, and making the country significantly more attractive as a destination for R&D investments in more segments that just IT should be an important policy objective for the government. This objective is unlikely to be achieved without significant improvements in the condition of Polish science and innovation environments.

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