

Economic impact of industry-sponsored clinical trials of medicinal products of the pharmaceutical sector in Austria

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Objectives

Modern medicinal product development is a long and complex process associated with significant investment needed by pharmaceutical companies. Despite the investment there is a high risk to fail during the development of effective and safe medicines. The innovative pharmaceutical industry accounts for the vast majority of investments in clinical-trials of potential new medicinal products and therefore generates economic activity within a country. The aim was to assess the far-reaching economic impact of industry-sponsored clinical-trials of medicinal products for the health care system and the national economy in total.

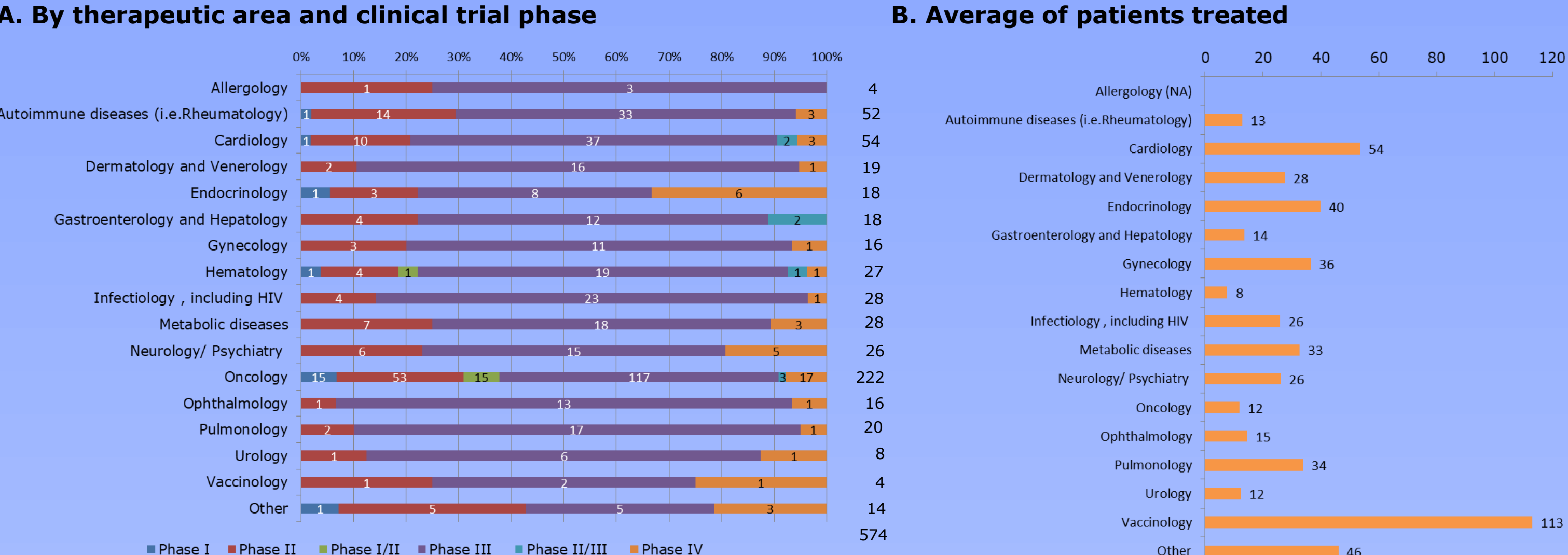
Methods

- The study approach was based on three analytical steps.
- First, a survey among 15 pharmaceutical companies was conducted to evaluate the annual number of industry-sponsored clinical-trials subdivided according trial phase, therapeutic areas and associated employees.
 - Second, the monetary value of treatments performed in industry-sponsored clinical-trials was calculated based on a sample of clinical-trial protocols.
 - Finally, the macroeconomic impact, measured in terms of value-added and jobs created by the conducted industry-sponsored clinical-trials, was calculated using Input-Output analysis by applying an extended Leontief-model.

Evaluation of industry-sponsored clinical trials

To provide a detailed analysis of industry-sponsored clinical trials, a representative list of industry-sponsored clinical trials has been compiled by Austrian affiliates of 15 international pharmaceutical companies, covering 82.5% of industry-sponsored clinical trials in Austria. This list included a sample of 574 clinical trials (56% of the total statistical population) conducted between 2012 and 2017. Of the 574 clinical trials, 155 were ongoing and 419 were completed (Fig. 1A). On average, 32 patients were enrolled at a clinical trial site per industry-sponsored clinical trial. As expected, the numbers vary significantly among therapeutic areas, ranging from an average of 113 patients in the field of vaccinology to an average of 8 patients in hematology (Fig. 1B).

Fig. 1: Characteristics of industry-sponsored clinical trials in Austria



Source: own calculations

Over the considered time horizon (2012 to 2017) a total of 1,029 clinical trials were conducted. The multiplication by the average number of enrolled patients per therapeutic area yielded 23,331 patients treated in industry-sponsored clinical trials. This means that the calculated average of 463 clinical trials a year run on average for 34.7 months (first patient in to last patient out). From an annual perspective, patients were treated on average for 5.8 months within a year. To calculate the human resources and costs for conducting clinical trials, data from 5 pharmaceutical companies was analyzed as well as average gross production values per capita was used.

Calculation monetary value of treatments performed

In order to determine the value of the medical treatment provided by clinical research, it was necessary to draw a representative sample from the list of 574 clinical trials. A sample of clinical trials was selected in the form of "cluster sampling" (according therapeutic areas and trial phases). 90 trials were randomly selected. The distribution of therapeutic areas and phases of the sample corresponded to the totality of clinical trials. To determine the sample size, a 95% confidence interval [95% CI] and a standard error of 10% was used. The financial assessment of treatment services rendered in industry-sponsored clinical trials was based on the clinical trial protocols of the 90 representative clinical trials. Each service rendered was quantified and cost-assessed using reimbursement rates (prices, tariffs and/or lump sums). The reimbursement amounts were derived from official Austrian price lists and represented costs for the year 2018; collected from the payer's perspective.

The procedure for determining the medical costs is as follows:

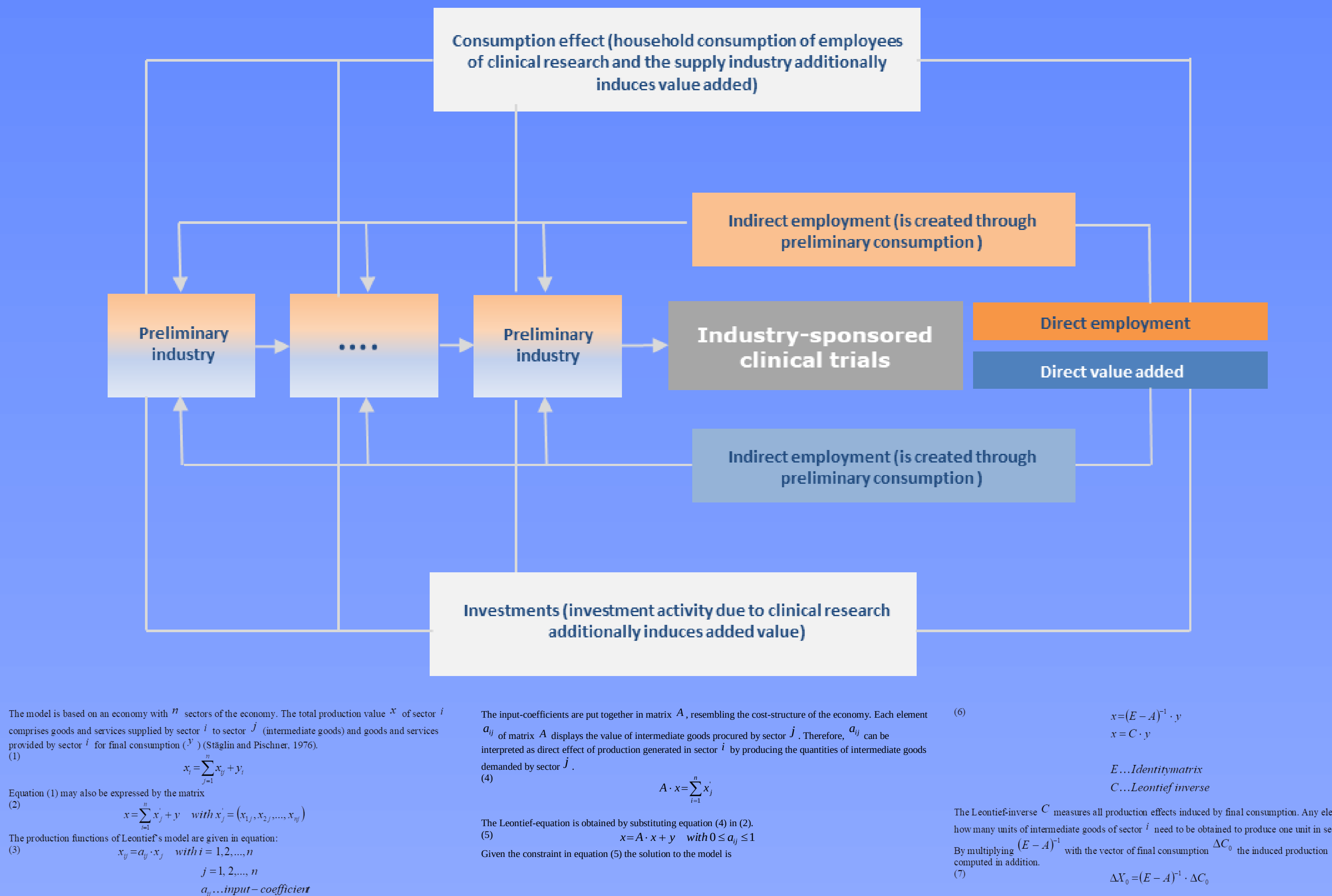
- All medical services were identified from the clinical trial protocols, which comprises all services under the clinical trial protocol from the medicinal products, laboratory testing prior and after drug application, treatment monitoring and monitoring of adverse events.
- The frequencies of the services provided are recorded over the clinical trial follow-up. For completed clinical trials, the actual study duration and number of patients were used; for the ongoing clinical examinations the planned duration of study and number of patients.
- The unit costs for each medical service were determined.
- The unit costs corresponded to the reimbursement rate that would be reimbursed by social insurance if the treatment is not performed within a clinical trial.
- The reimbursement amounts were derived from the official Austrian price lists of health insurance funds, the outpatient clinic catalogue as well as from the Austrian positive list for medication.
- The assessment of costs was performed in accordance with the guidelines of the IQWiG (General Methods Version 5.0, Chapter Costs) and the ISPOR Good Research Practices .
- A conservative cost assessment was carried out. This means for example that cheaper unit costs were used instead of a lump sum (for example, infusion costs for a cancer therapy instead of a day clinic).
- The cost evaluation was based on 2018 costs.
- Depending on the setting, medication was valued with the corresponding price level; the ex-factory price was used for medication administered in hospital and the health insurance price was used for medication administered in the outpatient setting.
- If the clinical trial was ongoing and the investigational drug not yet approved, the cost of the current Standard of Care (SoC) often administered in the placebo arm was used for the assessment.
- Medication costs for placebo (ineffective substances) were not assessed.
- In the case of a single-arm trial and a not yet approved substance, the SoC had to be determined using treatment guidelines.
- Total costs per patient were determined
- The number of patients enrolled (planned) per clinical trial were reported to determine the cost per clinical trial.
- The direct medical costs were charged per clinical trial - over the entire study period and per month.
- Furthermore, the average costs per clinical trial of a therapeutic area were recorded.

Calculation monetary of macroeconomic impacts

The macroeconomic impact is measured in terms of value added and jobs created by the industry-sponsored clinical trials using Input-Output analysis by applying an extended Leontief-model (Leontief and Keynesian multiplier). The model is based on a national concept, e.g. the effects of imports and exports are not observed. It analyses economic effects generated on three different levels: Level one; direct effects on value added and employment – expressed in FTEs – are created due to the clinical trials. Level two; to perform their tasks, operating sites need intermediate goods, medicinal products, IT-services, and electricity etc. Due to the various interconnections between the operating sites and its supplying industries, industry-sponsored clinical trials also generate jobs and value added in these preliminary sectors.

Level three; induced effects occur through employees' consumption and purchase of goods and services provided by industry-sponsored clinical trials and its supplying industries, e.g. they spend their salaries to finance their living, buy clothes, and food etc. Consumption therefore generates value added and jobs in business sectors apart from clinical research. The second source of induced effects comes from investments due to industry-sponsored clinical trials and preliminary industries.

Fig. 2: Overview of economic effects of industry-sponsored clinical trials on the overall economy



Source: own developed, Stäglin & Pischner 1976

Results

Looking at the total expenditure for medical treatments in industry-sponsored clinical trials during the 2012 to 2017 observational period, the figure amounted to € 603.93 million. The expenditure for medical treatments comprises all services under the clinical trial protocol and not just the clinical trial medicinal products. The value of medical treatments was borne by the pharmaceutical industry as sponsors of the clinical trials and thus relieved the healthcare system. During the 2012 to 2017 observational period, an average of 23,331 patients was treated in 1,029 clinical trials. Each year a medical treatment value of € 100 million was financed through 463 industry-sponsored clinical-trials with an average value of medical treatment of € 37,068 per recruited patient. This represents a significant 0.3% of annual current health expenditures.

Fig. 3A: Annual value of medical treatments by therapeutic area in Euros (total 100.53 million)

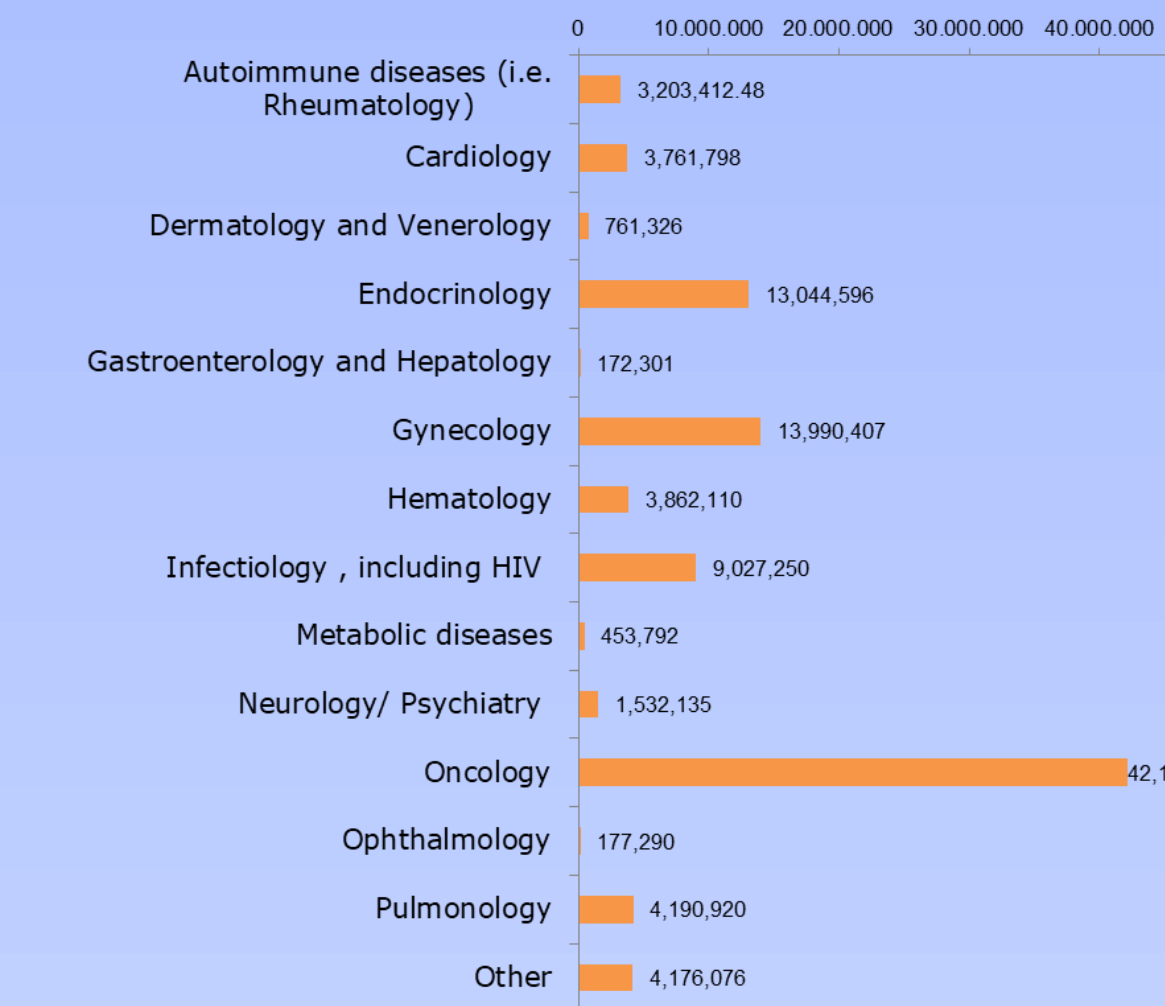
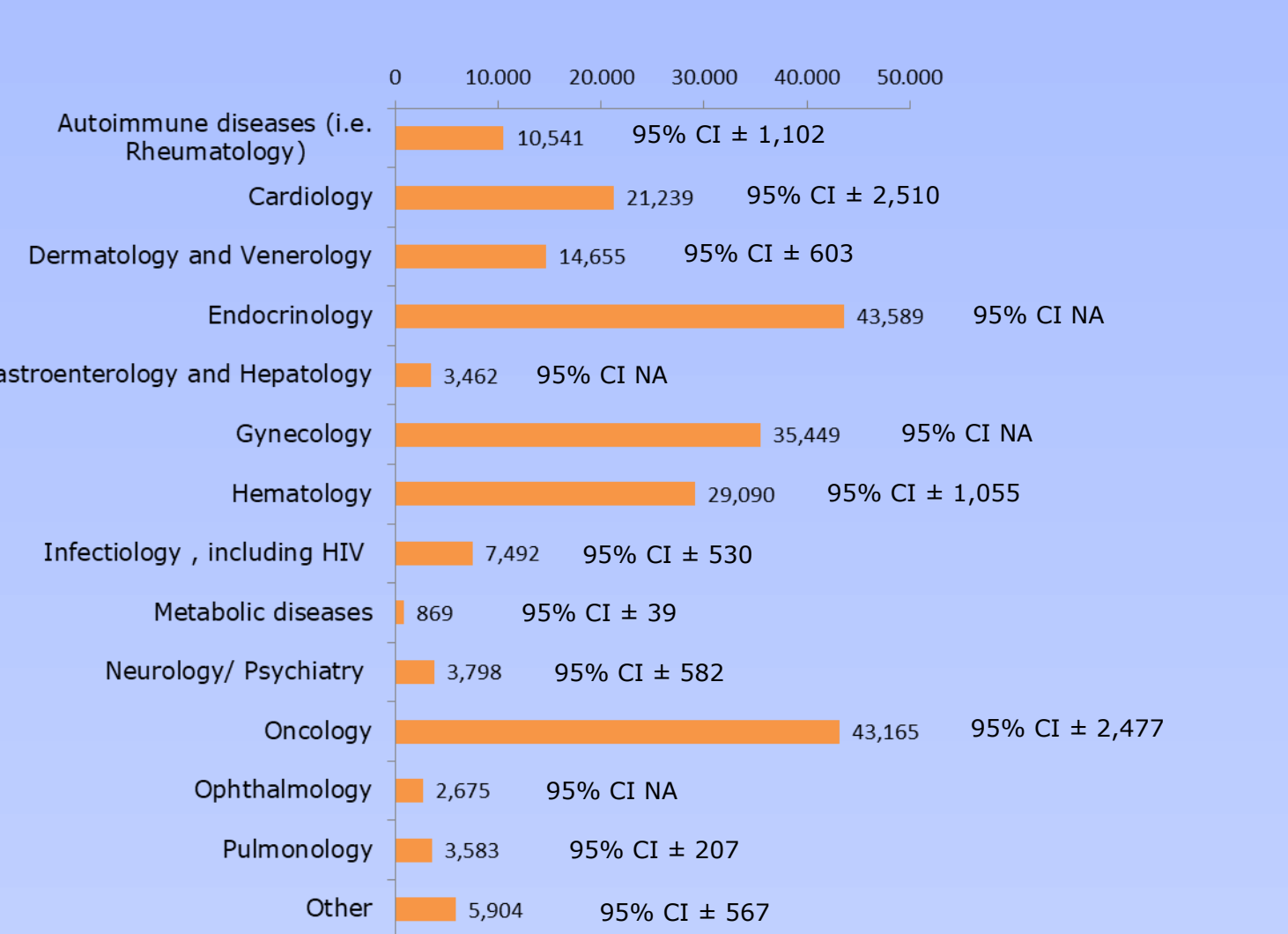


Fig. 3B: Medical treatment costs per year and per patient by therapeutic area in Euros



Source: own calculations

The study demonstrated that industry-sponsored clinical-trials generated a total value added of € 144 million in 2018 in Austria. In summary, each Euro invested by the pharmaceutical industry in clinical trials generates € 1.95 for the Austrian economy. Industry-sponsored clinical research also created and secured employment in the extent of 2,021 full-time-equivalents (FTE), thus resulting in an employment multiplier of 1.66.

Table. 2: Economic effects of value added and employment in 2018

Effects	Total value added	Total employment
Direct effect	€ 74.13 million	1,215 FTEs
Indirect effect	€ 38.47 million	475 FTEs
Induced effect	€ 31.60 million	331 FTEs
Total	€ 144.19 million	2,021 FTEs
Multiplier	1.95	1.66

FTE = full time equivalent
Source: own calculations

It is interesting to note that the results are relatively comparable to the Austrian tourism industry. The Austrian Institute for Economic Research (WIFO) calculated multipliers for the value added results of tourism amounting to 1.51 and for the employment of 1.85

Conclusion

In conclusion, conducting clinical-trials by pharmaceutical industry results in tangible benefits and positive macroeconomic impact that contribute to the sustainability of the Austrian health care system by complementing its limited resources.

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Additional Literature with the author

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