How can society benefit from clinical drug trials conducted in Finland?

# The societal value of clinical drug trials

Final report 11.6.2024,

English version 3.9.2024

**Also presented as a peer-reviewed poster presentation:**
Väätäinen S, Ehlers P, Tamminen N, Soini E. Direct and Indirect Benefits of Clinical Trials for the Public Health Care: Finnish Society Gains 10 Million Euros of Value per Trial. Value in Health 2024. [Poster presentation at the ISPOR Europe 2024 Congress].

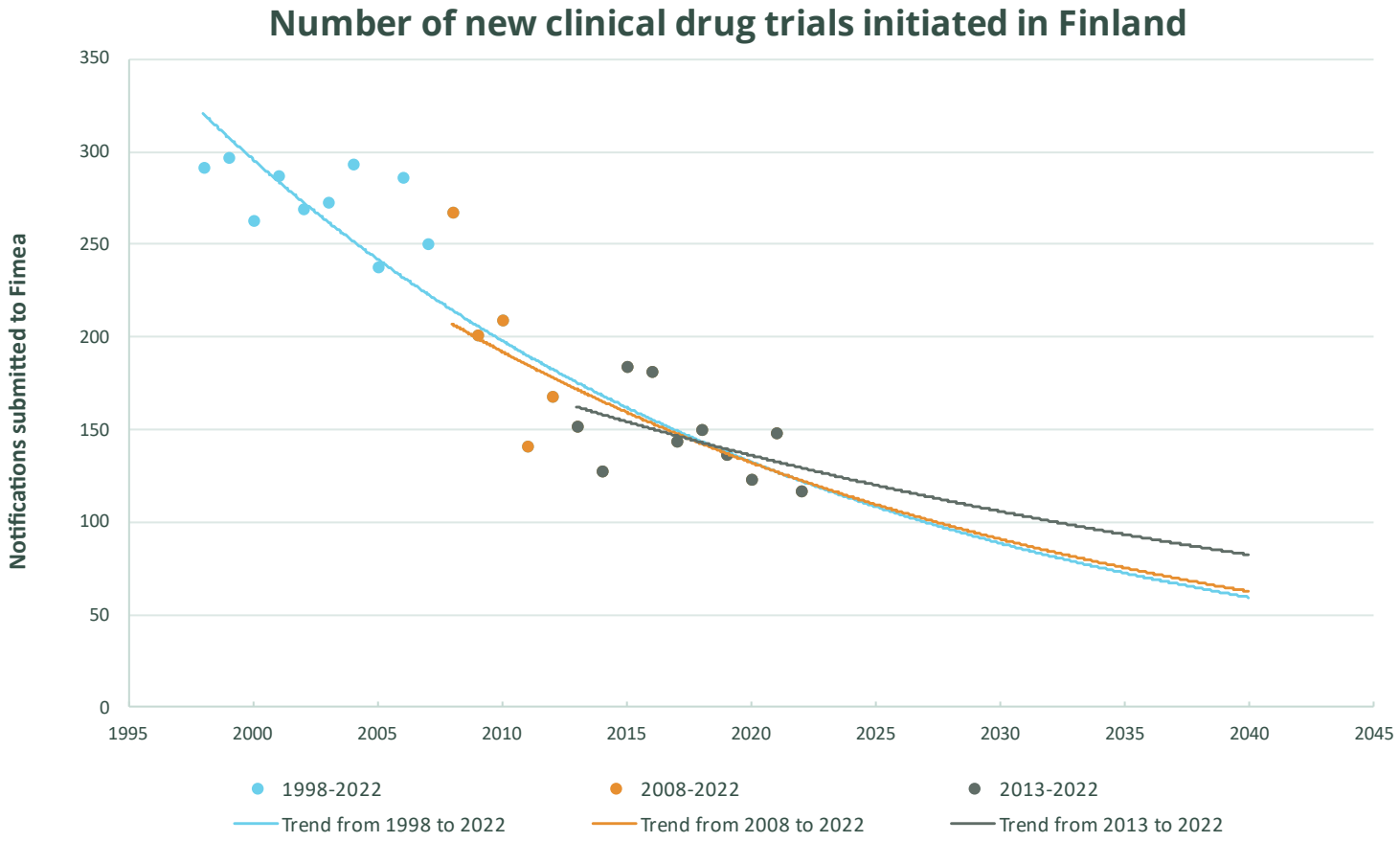
LääketeollisuusPharma Industry Finland

ESiOR

# Clinical drug research in healthcare

- **In clinical drug trials, the pharmaceutical company funding the study typically pays for the medications used to treat the participants, as well as the costs related to the treatment and monitoring of the subjects during the study.**
  - Clinical drug trials can help control healthcare costs.
- **However, the role of healthcare is not to minimize costs but to produce health for citizens.**
  - The quantity of health and the produced health benefits are often measured with quality-adjusted life years (QALY), which is calculated as the product of patients' quantity and quality of life.
  - The economic value of produced health can be expressed in monetary terms, when it is known how much society or the payer is willing to pay for one unit of health produced (the so-called "willingness-to-pay" threshold).
- **Clinical drug research is today's treatment — and the only treatment option for many patients.**
  - In addition to cost benefits, clinical drug research generates health benefits, not only for the patients participating in the trial, but also for the other patients treated in the hospital conducting the research. Trials increase the knowledge, skills, and clinical practice of the staff and organisation carrying out the research.

# The number of clinical drug trials conducted in Finland has been declining for more than 25 years




Number of studies notified to Fimea: Hoimalahti & Puomila 2008 [up to 1998 to 2007] and Fimea 2023 [2008 to 2022].
Trends and projections: ESiOR Oy.

- If the trend of the last 10 years continues, approximately 80 new clinical drug trials would be initiated in Finland in the year 2040.
- With the trends of the last 15-25 years, only 60 new clinical drug trials would be initiated in Finland in the year 2040.

# Evaluating the societal value of clinical drug trials

- **The objective of the present study was to evaluate the societal value of clinical drug trials conducted in Finland. Specifically, the aim was to answer the question: *How much value do these trials generate for Finnish society both in total and on average per trial?***

- **Both the direct value arising from the care provided to study subjects in the trials and the broader societal value, considering indirect value generated elsewhere in healthcare, were considered in the evaluation.**
  - When a patient participates in a clinical drug trial, direct value is gained from the treatment and monitoring covered by the contract payments from the study sponsor, drugs paid by the study sponsor, and the health benefits experienced by the patients participating in the study.
  - Other societal value included the cost and health benefits generated elsewhere in healthcare.
  - The evaluation describes the average gross value of a clinical drug trial conducted in Finland.

- **The evaluation model was based on a survey of Finnish hospitals conducted in spring 2024, annual surveys of member companies by Pharma Industry Finland (PIF), and publicly available literature, data, and statistics.**

# Key findings

- **Conducting clinical drug trials in Finland generates significant direct and indirect societal benefits.**
  - The average value of care provided in one clinical drug trial averages around €1.2 million per trial.
  - The societal value of one clinical drug trial averages approximately €10 million.
  - For the clinical drug trials initiated between 2018 and 2023, the average value of care provided in the initiated trials was around €107 million and the societal value to healthcare around €880 million annually.

- **If the long-term decline in the initiation of clinical drug trials continues, the annual number of new clinical drug trials in Finland could halve by 2040.**
  - Finnish society could lose hundreds of millions worth of cost and health benefits from the care provided in clinical drug trials.
  - When the indirect value generated elsewhere in healthcare, including value of accumulated knowledge, experiences and improvements in clinical practices, are estimated even conservatively, the potential lost societal value rises to billions.

# Source material used in the modelled evaluation

## Publicly available material


- Alanne et al. 2015. Estimating the minimum important change in the 15D scores. Available: https://doi.org/10.1007/s11136-014-0787-4
- Claxton et al. 2015. Methods for the Estimation of the NICE Cost Effectiveness Threshold. Available: https://doi.org/10.3310/hta19140
- Cohen et al. 2019. Putting The Costs And Benefits Of New Gene Therapies Into Perspective. Available: https://www.healthaffairs.org/do/10.1377/forefront.20190827.553404
- Fimea 2023 Lääketutkimuksen tilasto 2022 [in Finnish]. Available: https://fimea.fi/-/kliinisten-laaketutkimusten-tilasto-2022-on-valmistunut
- Lichtenberg 2014. The Impact of Pharmaceutical Innovation on Disability Days and the Use of Medical Services in the United States, 1997–2010. Available: https://www.journals.uchicago.edu/doi/10.1086/679110
- Lichtenberg 2019. The Impact of New Drug Launches on Hospitalization in 2015 for 67 Medical Conditions in 15 OECD Countries: A Two-Way Fixed-Effects Analysis. Available: https://doi.org/10.1515/fhep-2018-0009
- Lichtenberg 2023. The Relationship Between Pharmaceutical Innovation and Cancer Mortality in Spain, From 1999 to 2016. Available: https://doi.org/10.1016/j.jval.2023.08.011
- Hoimalahti & Puomila 2008. Clinical trials in Finland 2007. Tabu 2008. Available: https://www.julkari.fi/handle/10024/122062
- THL. Tietokantaraportit, erikoissairaanhoidon palvelut [in Finnish and Swedish]. Available: https://sampo.thl.fi/pivot/prod/fi/thil
- Wong et al. 2019. Estimation of clinical trial success rates and related parameters. Available: https://doi.org/10.1093/biostatistics/kxx069


## Unpublished data on-file

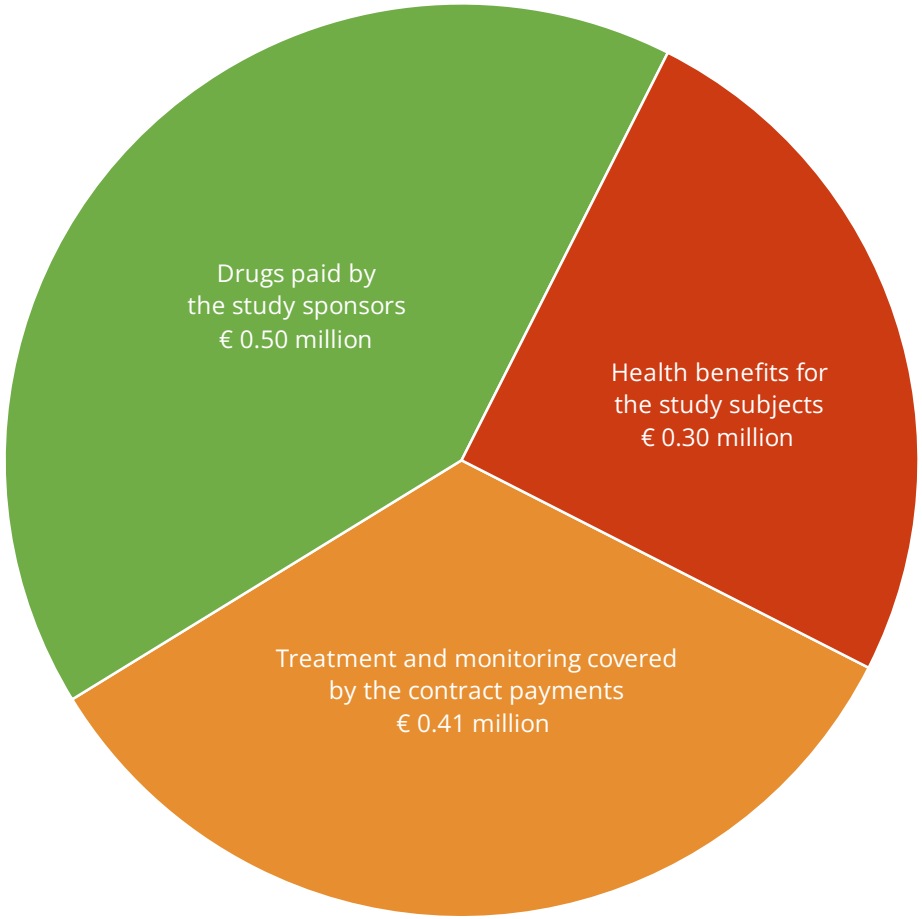
- Survey to Finnish hospitals conducted in Spring 2024.
- Pharma Industry Finland (PIF) surveys to member companies in 2018-2022. (Latest public reports available online: https://www.pif.fi/newsroom/statistics.html)

# Results

Lääketeollisuus
Pharma Industry Finland

ESIOR

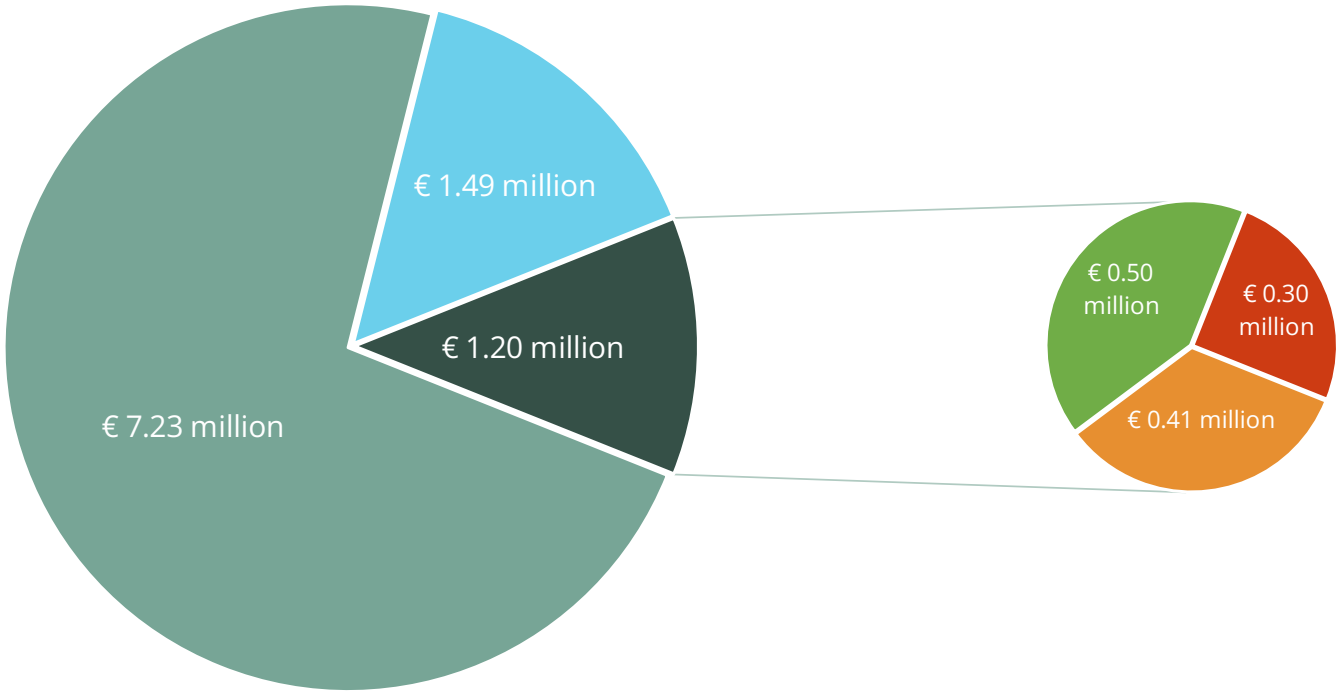
# The average value of care provided in a clinical drug trial was approximately €1.2 million




## The value of care provided to study subjects:

- Drugs paid by the study sponsors 41 %
- Treatment and monitoring covered by the contract payments 34 %
- Health benefits for the study subjects 25 %

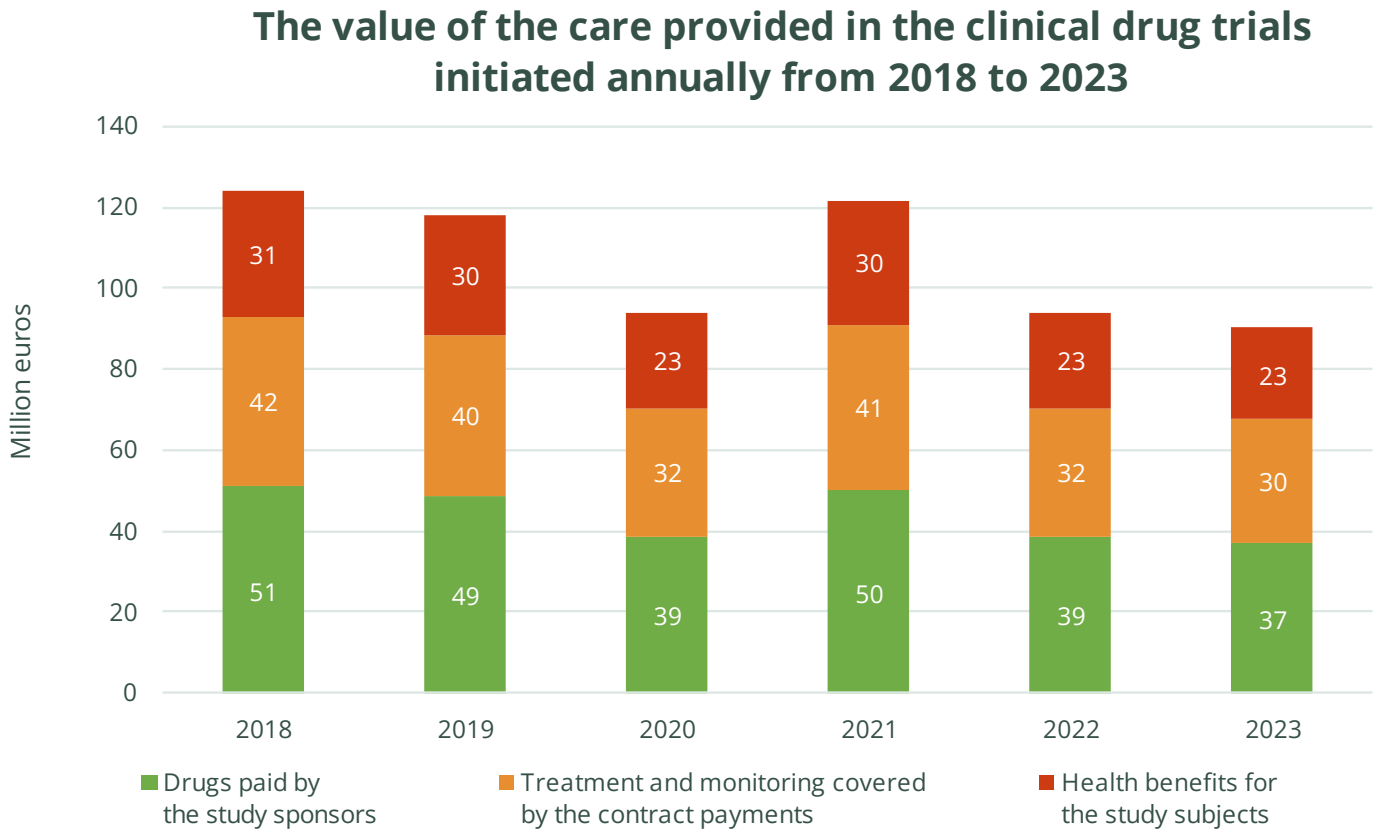
# The societal value of one clinical drug trial to healthcare averaged around €10 million




## The societal value of a clinical drug trial:

- Health benefits elsewhere in healthcare 73 %
- Cost benefits elsewhere in healthcare 15 %
- Drugs paid by the study sponsors 5 %
- Treatment and monitoring covered by the contract payments 4 %
- Health benefits for the study subjects 3 %

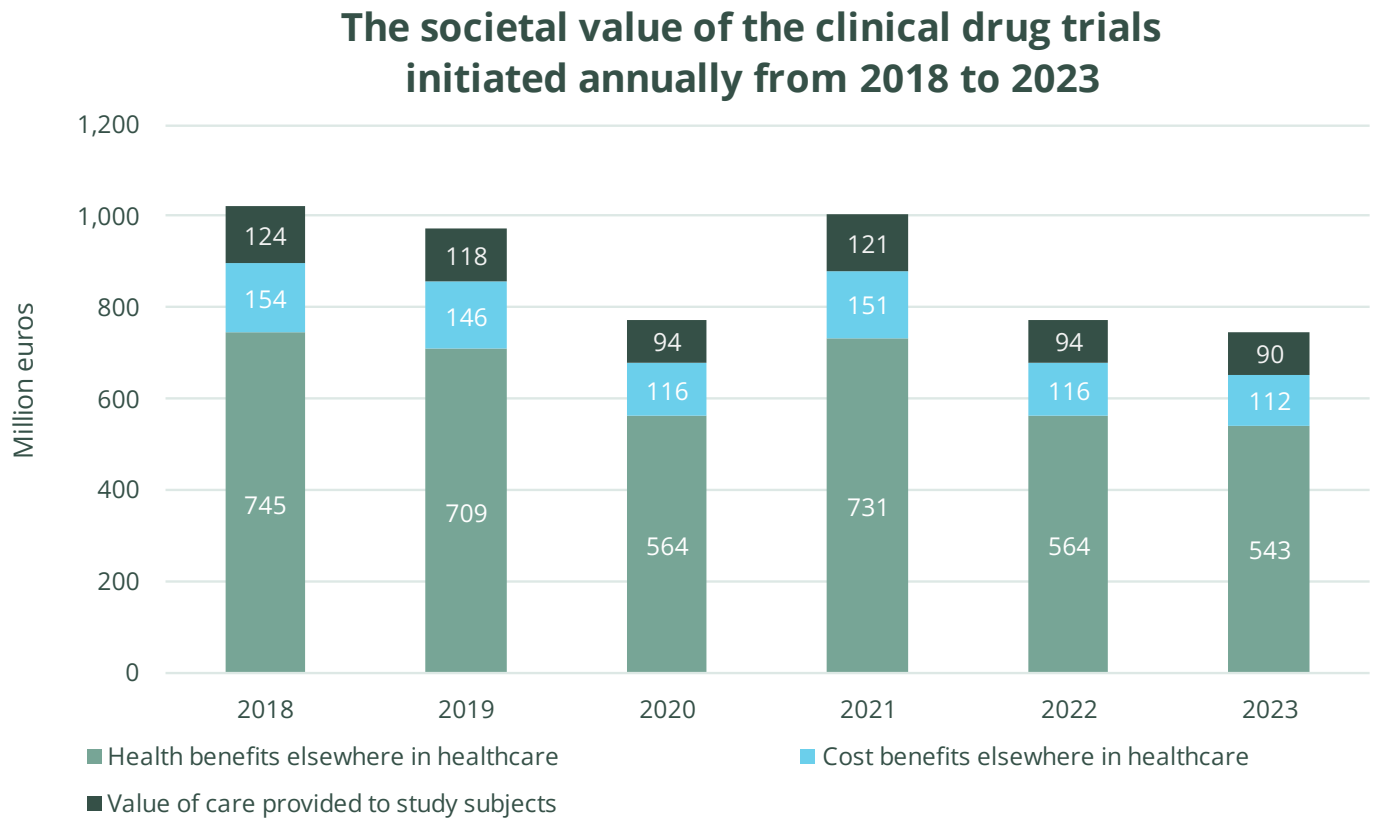
# From 2018 to 2023, the value of care provided in the initiated clinical drug trials was around €107 million annually




## The value of care provided to study subjects:

- Drugs paid by the study sponsors 41 %
- Treatment and monitoring covered by the contract payments 34 %
- Health benefits for the study subjects 25 %

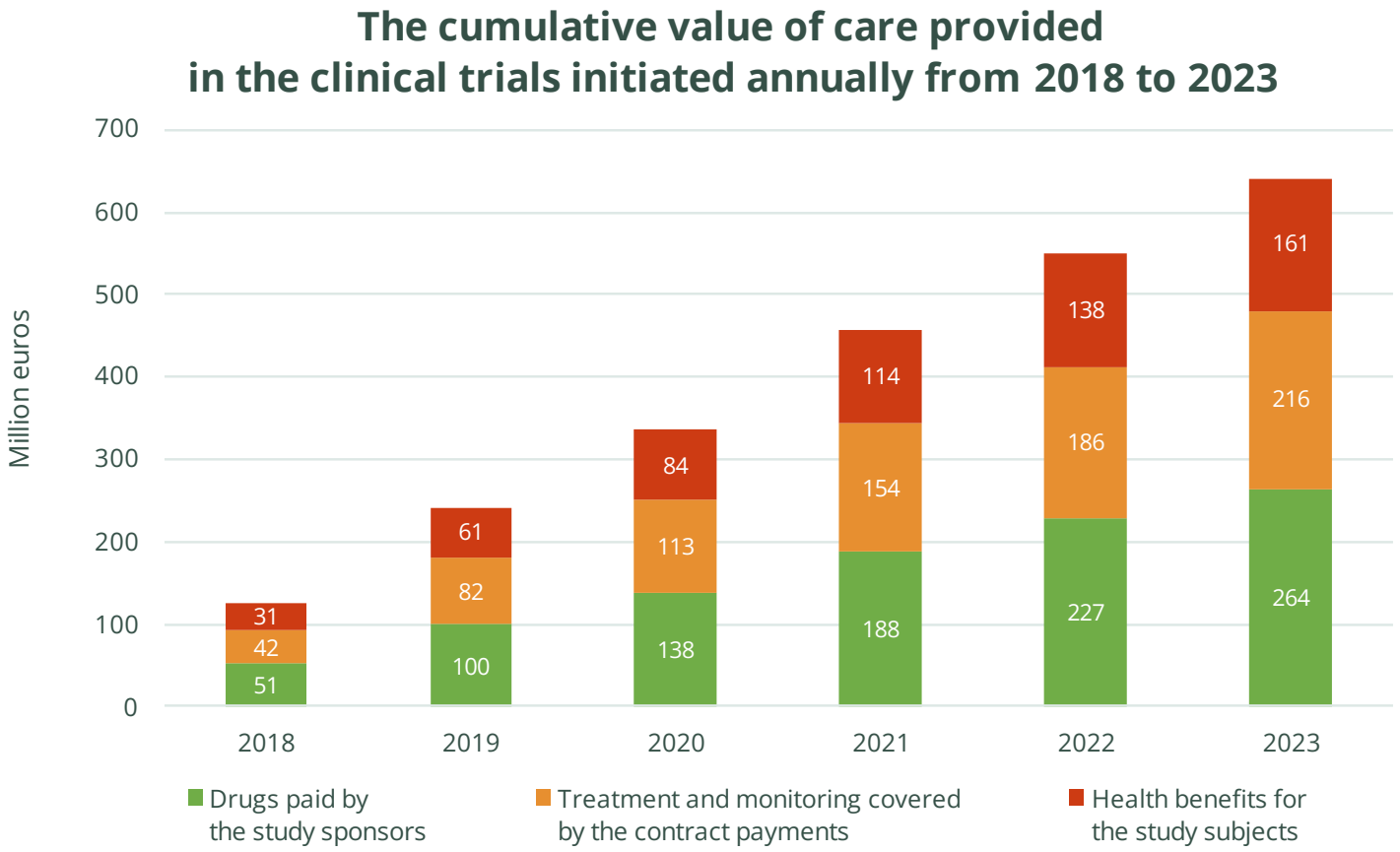
# From 2018 to 2023, the societal value of the initiated clinical drug trials was around €880 million annually




## The societal value of a clinical drug trial:

- Health benefits elsewhere in healthcare 73 %
- Cost benefits elsewhere in healthcare 15 %
- Drugs paid by the study sponsors 5 %
- Treatment and monitoring covered by the contract payments 4 %
- Health benefits for the study subjects 3 %

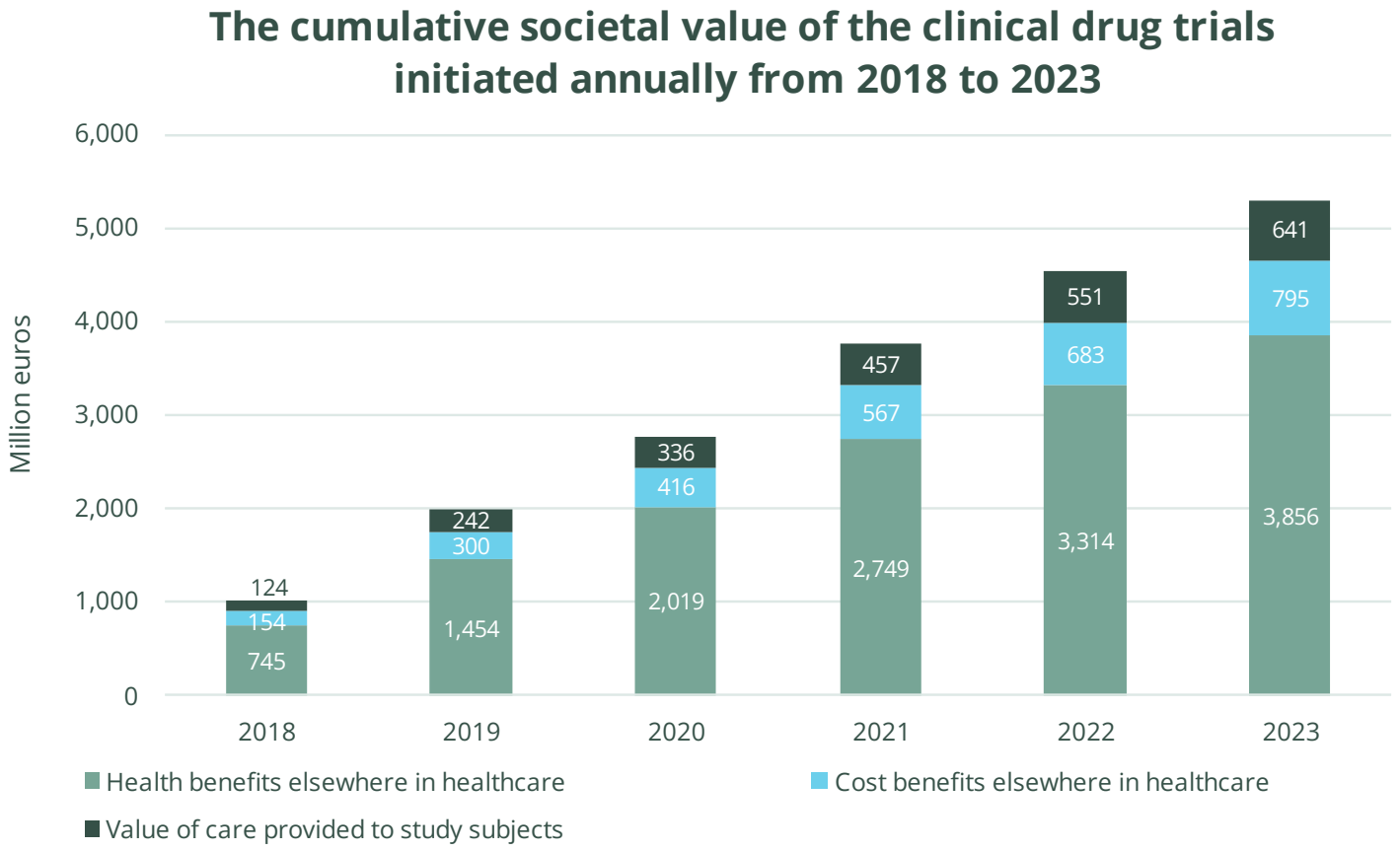
# The cumulative value of care provided in the clinical drug trials initiated annually from 2018 to 2023 was around €640 million




## The value of care provided to study subjects:

- Drugs paid by the study sponsors 41 %
- Treatment and monitoring covered by the contract payments 34 %
- Health benefits for the study subjects 25 %

# The cumulative societal value of the clinical drug trials initiated annually from 2018 to 2023 was approximately €5.3 billion




## The societal value of a clinical drug trial:

- Health benefits elsewhere in healthcare 73 %
- Cost benefits elsewhere in healthcare 15 %
- Drugs paid by the study sponsors 5 %
- Treatment and monitoring covered by the contract payments 4 %
- Health benefits for the study subjects 3 %

# Materials and methods

Lääketeollisuus
Pharma Industry Finland

ESIOR

# Annual surveys to member companies by Pharma Industry Finland in 2018-2022

Lääketeollisuus
Pharma Industry Finland

ESIOR

# Annual Pharma Industry Finland surveys in 2018–2022 – Respondents and clinical drug research in Finland

Every year, Pharma Industry Finland sends a survey to its member companies inquiring about, among other factors, the number of trials, the number of subjects in the studies, and the companies' investments in research and development. For the present evaluation, observations from 2018 to 2022 were examined. During this period, 20-25 pharmaceutical companies responded to the annual surveys each year.

- **Between 2018 and 2022, the respondent companies had notified a total of 309 clinical drug trials to Fimea, representing 60 % of all commercial clinical drug trials notified to Fimea during this period (N=515).**
- **On average, companies reported a total of 220 (191-256) clinical drug trials ongoing annually. For each new clinical drug trial notified to Fimea, there were on average 3.55 ongoing clinical drug trials (averaging annually 2.69-4.27).**
- **The respondent companies reported having invested a total of €359.3 million in clinical drug research from the year 2019 to 2022.**
- **The respondent companies reported having invested a total of €1.14 billion in research and development during this period.**

# Annual Pharma Industry Finland surveys in 2018–2022 – Clinical drug trial participants

- **7,585 to 43,514 subjects participated in the ongoing clinical drug trials annually.**

- **While vaccine trials represented 11 % of the ongoing clinical drug trials, vaccine trials comprised 91 % of all subjects participating in the ongoing clinical drug trials.**
  - On average, 1,037 subjects took part in each ongoing vaccine trial (annual averages ranged from 444 to 2,325).
  - Other clinical drug trials had an average of 12.3 participants (annual averages ranged from 9.1 to 17.4).
  - On average, 2.6 study sites participated in ongoing drug trials (annual averages ranged from 2.5 to 2.8).

# Survey to Finnish hospitals in Spring 2024

Lääketeollisuus
Pharma Industry Finland

ESIOR

# Survey to Finnish hospitals – Target group and respondents

ESiOR and Pharma Industry Finland addressed a survey and data request to Finnish hospitals and healthcare organisations in Spring 2024. In addition to background information, the survey included questions about the number of initiated and ongoing clinical drug trials, the number of trial participants, research funding, research infrastructure, as well as how clinical drug research had impacted the organisation, and the patients treated in the organisation.

- **The survey was sent to a total of 30 public healthcare organisations across all wellbeing service counties, including:**
  - Every central hospital in mainland Finland and Åland (n=16).
  - University hospitals (n=5).
  - Hospitals operating under the National Institute for Health and Welfare (THL, n=5).
  - Additionally, the survey was sent to four wellbeing service counties in Southern Finland that do not have a central hospital.
- **A total of 20 organisations responded to the survey.**
  - 1 central hospital declined to participate, and 9 organisations did not respond to the invitation or any of the three (3) reminders sent.
  - Of the responding organisations, 5 were university hospitals (response rate was 100 % for this organisation type), 9 were central hospitals (56 %), 3 hospitals operated under THL (60 %) and 3 were wellbeing service counties in Southern Finland without a central hospital (75 %).

# Survey to Finnish hospitals – Clinical drug trials conducted in public hospitals

- **Most of the clinical drug trials were conducted in university hospitals. Of all the responding organisations, 10 (50 %) reported clinical drug research being conducted in the organisation at the time of the survey.**
  - All Finnish university hospitals conduct clinical drug trials.
  - Five (56%) of the responding central hospitals conducted clinical drug trials.
    - Of the nine central hospitals responding to the survey, four (44%) stated that no pharmaceutical research was conducted at the hospital at the time of survey. Of these, 3 reported that clinical trials involving only a few subjects had been conducted sporadically earlier during the period under evaluation (2018-2022).
  - All three hospitals operating under the National Institute for Health and Welfare (THL) that responded to the survey reported that no clinical drug trials were being conducted.
  - The responding wellbeing service counties of Southern Finland did not carry out clinical drug trials at the time of the survey.
- **Of the 10 organisations conducting clinical drug trials, a total of 9 hospitals (5 university hospitals and 4 central hospitals) returned the completed survey form with their responses.**

# Survey to Finnish hospitals
# – Industry-sponsored clinical drug trials

- **A total of 52 annual observations (96.3%, N=54) were received from the nine responding hospitals concerning the total annual amounts of contract payments for the industry-sponsored clinical drug trials over the six years reviewed (2018-2022).**

- **These hospitals reported having received a total of €84.1 million in payments for industry-sponsored clinical trials during the period.**

- **During the reviewed period, the hospitals reported initiating* a total of 723 industry-sponsored clinical drug trials (n=53/54) and 262 academic drug trials (n=49/54).**

* The same study may have started or been ongoing in several hospitals at the same time. Based on the Pharma Industry Finland surveys, an average of 2.6 study sites are involved in one study.

# Survey to Finnish hospitals
## – Contract payments covering the costs of industry-sponsored trials

- In addition to annual total contract payments received for the industry-sponsored clinical drug trials, four organisations provided a total of 27 annual observations of the number of subjects in the ongoing clinical drug trials. For other hospitals that provided information on total annual contract payments, the average annual payments per study subject were estimated based on the number of ongoing and initiated clinical drug trials, if this information was available (n=22).
- **The average annual payments from the study sponsors per study subject in an ongoing trial was estimated at €9,840.**

**Average annual contract payments from the study sponsors per study subject in an ongoing clinical drug trial.**

| Method used to estimate the number of participants | Mean | SE | Median | Minimum | Maximum |
|---|---|---|---|---|---|
| Number of trial participants reported by the hospital (n=27) | €10,906.53 | €2,012.72 | €7,634.07 | €575.32 | €43,629.86 |
| Estimated based on the number of ongoing clinical drug trials (n=35) | €8,604.91 | €1,497.53 | €4,940.43 | €1,199.58 | €38,273.27 |
| Estimated based on the number of initiated clinical drug trials (n=44) | €6,935.37 | €595.38 | €6,032.71 | €1,372.14 | €21,448.99 |
| **Estimates used in the modelled analyses (n=49)** | **€9,839.92** | **€1,231.94** | **€7,148.81** | **€575.32** | **€43,629.86** |

For each ongoing industry-sponsored clinical drug trial, there was an average of 4.7 (0.9-9.8) subjects participating in the trials. For each initiated clinical drug trial, there were on average 19.2 (4-59) subjects.

# Survey to Finnish hospitals – Drugs paid by the study sponsors

- The value of the drugs paid by the study sponsors received in the clinical drug trials had been assessed in five hospitals that responded to the survey, which **reported a total value of €71.9 million (n=22).** From these hospitals, the numbers of trial participants were available from the corresponding years for 14 annual observations. For other hospitals, the value of drugs per study subject was based on the number of ongoing and newly initiated studies.
- **The average annual value of drugs paid by the study sponsors per study subject in an ongoing trial was estimated at €12,023.**
- These estimates include only drugs that were delivered through the hospital dispensary, were already on the market, and had a market price. None of the estimates include so-called unpriced drugs that are not yet on the market. **Thus, the estimates presented below are very conservative**. If only university hospitals are considered in the analysis, the average estimated value of drugs is €19,358 per study subject.

**Average annual value of drugs paid by the study sponsors per study subject in an ongoing clinical drug trial.**

| Method used to estimate the number of participants | Mean | SE | Median | Minimum | Maximum |
|---|---|---|---|---|---|
| Number of trial participants reported by the hospital (n=14) | €10,063.46 | €4,267.25 | €2,568.57 | €0.00 | €56,250.00 |
| Estimated based on the number of ongoing clinical drug trials (n=17) | €8,314.49 | €2,169.81 | €5,834.90 | €0.00 | €25,038.69 |
| Estimated based on the number of initiated clinical drug trials (n=19) | €11,215.05 | €2,003.09 | €9,776.74 | €0.00 | €31,257.20 |
| **Estimates used in the modelled analyses (n=22)** | **€12,023.23** | **€2,893.84** | **€8,300.38** | **€0.00** | **€56,250.00** |

For each ongoing industry-sponsored clinical drug trial, there was an average of 4.7 (0.9-9.8) subjects participating in the trials. For each initiated clinical drug trial, there were on average 19.2 (4-59) subjects.

# Survey to Finnish hospitals – Effects of clinical drug trials

- **All nine hospitals that returned a completed survey form answered questions regarding the impact of the clinical drug research on the organisation's operational capabilities, the treatment outcomes, the quality of life of the patients treated in the organisation, and how much clinical drug research would be conducted in the organisation, if the internal resources were not a constraint.**
  - All hospitals that completed the questionnaire (n=9) responded that clinical drug trials improve the organisation's operational capabilities.
  - 89% responded that the clinical drug trials improve the treatment outcomes for patients treated in their organisation; 11% were unsure.
  - 67% responded that the clinical drug improves the quality of life of patients treated in their organisation; 33% were unsure.
  - All respondents would conduct significantly more clinical drug research, if they could decide how many clinical trials are conducted in the hospital, and the internal resources were not a constraint.

# The decision-analytic model for evaluating the societal value of clinical drug trials

Lääketeollisuus
Pharma Industry Finland

ESIOR

# Scope of the evaluation

- **The evaluation examines the societal impacts of industry-sponsored clinical drug trials conducted in Finland in the current situation compared to the scenario where no clinical drug trials are conducted.**
- The evaluation does not consider the benefits of new medicinal products entering the market or the value of new medicinal products after they have received marketing authorisation. These benefits can be assumed to be obtained even if the clinical trials were conducted outside Finland.
- The modelled results answer the question of ***how much social value (benefit) is generated by conducting a clinical trial funded by a pharmaceutical company in public healthcare in Finland?***
- Vaccine trials were not included in the evaluation.
- Paediatric drug trials could not be excluded nor specifically examined, so they could not be examined comprehensively.

# Scope of the evaluation
# – Vaccine trials were not included

- **Clinical vaccine trials differ significantly from other clinical drug trials**
  - Vaccines are not used to treat an existing condition, but instead aim to prevent the onset or transmission of the disease.
  - The benefits of conducting vaccine trials come from avoided events that would have been associated with the prevented disease, as well as the knowledge and expertise generated by conducting vaccine research.
  - Small children and elderly are overrepresented in the vaccine trials compared to other clinical drug trials.
  - The number of study subjects is typically much higher than in other clinical drug trials.
- **Estimating the benefits and value of clinical vaccine trials is not as straightforward as evaluating the value of other clinical trials and would require more information and assumptions about the (average) benefits of vaccines under development.**

# Scope of the evaluation
# – Paediatric drug trials could not be evaluated comprehensively

- **Paediatric drug trials are conducted relatively infrequently, and unfortunately, there is very little generalisable or comprehensive data available from them.**
- **The Finnish hospitals participating in our survey generally could either not provide the data on the number of clinical drug trial participants aged under 18 years old, or the numbers of paediatric participants were very small.**
- **Consequently, clinical drug trials including only paediatric participants could not be excluded from the evaluation, nor could they be examined specifically or comprehensively.**

# Scope of the evaluation
# – Academic, investigator-initiated clinical drug trials

- **Although the evaluation was limited to industry-sponsored drug trials funded by pharmaceutical companies, this does not mean that the role of academic and investigator-driven drug research is insignificant or minor.**
  - About one-quarter of the clinical drug trials conducted in Finland are non-commercial, academic, or investigator-initiated.
  - The benefits of knowledge, experience, and improved clinical practices accumulated from conducting academic and investigator-initiated trials can be assumed to be similar to the industry-sponsored trials.
  - On the other hand, it should be noted that pharmaceutical companies also provide drugs for investigator-initiated trials.

- **The evaluation was limited to industry-sponsored trials.**
  - When the research is funded by the public sector or a public sector-dependent entity, the perspective of the analysis determines whether the funds used to finance the trial are expenditure or income.
  - In contrast, the funding and fees paid by a private company to a public sector hospital carrying out the trial are always income from a societal, public healthcare payer perspective.

# Evaluation in the PICOSTEPS* Framework

| PICOSTEPS | Patients-Intervention-Comparators-Outcomes-Setting-Time-Effects-Perspective-Sensitivity |
|---|---|
| P: Population | Public healthcare patients participating in industry-sponsored clinical drug trials conducted in Finland (i.e. study subjects), and the other patients treated in hospitals carrying out clinical drug trials, who are subject to indirect effects of clinical drug trials. |
| I: Intervention | Industry-sponsored clinical drug trials conducted in Finland. |
| C: Comparator | Counterfactual scenario, where industry-sponsored clinical drug trials are not carried out in Finland. |
| O: Outcomes | Economic value of the clinical drug trials, in monetary terms:<br>• the average value per trial<br>• in total on a societal level |
| S: Setting | Analysis of the observable realized effects and value based on available historical data. |
| T: Time | Realized value and sources: Past 6 years (2018-2023).<br>Analyses were carried out using annual model cycles; continuation corrections or discounting was not applied. |
| E: Effects | Direct value of care provided to patients participating in clinical drug trials:<br>• Treatment and monitoring covered by contract payments (payments from sponsor for care, monitoring, and procedures conducted during the trial)<br>• Drugs paid by the study sponsors (study sponsor pays for the drugs administered during the trial)<br>• Health benefits for the study subjects<br><br>Benefits obtained elsewhere in healthcare:<br>• Cost benefits elsewhere in healthcare<br>• Health benefits elsewhere in healthcare |
| P: Perspective | Societal perspective. |
| S: Sensitivity analyses | Not conducted. |

*PICOSTEPS :http://www.kaypahoito.fi/web/kh/suositukset/suositus?id=nix02465&suositusid=hoi50062;https://www.clinicaltherapeutics.com/article/S0149-2918(17)30074-7/abstract; https://www.dovepress.com/articles.php?article_id=38587

# Average clinical drug trial – excluding vaccine trials

- **Between 2018 and 2023, 75-103 trials were initiated annually in Finland. [1]**
- **On average, ongoing studies included 12.3 subjects. [2]**
- **The average duration of a clinical drug trial is 3.35 years. [3]**

1) Survey to Finnish Hospitals 2024: There were, on average, 4.7 trial participants for each ongoing clinical drug trial; Pharma Industry Finland surveys: On average, 2.6 study sites participated in one clinical drug trial (4.72*2.60 = 12.3). Pharma Industry Finland surveys: From 2018 to 2022 the average number of study participants was 12.3 subjects per ongoing trial (excluding vaccine trials).
2) Medians for Phase I-II trials: 1.61, 2.94, and 3.84 years (Wong et al. 2019, https://doi.org/10.1093/biostatistics/kxx069); Average duration was weighted using statistics from Fimea (2023). Phase IV trials were modelled to have the same duration as Phase III trials (3.84).
3) Years 2018-2022 are estimated based on statistics from Fimea (2023) and Pharma Industry Finland surveys. Year 2023 was extrapolated based on the number of clinical trials reported by the hospitals participating in our survey to Finnish hospitals in spring 2024.

# Modelled effects and value drivers – Benefits from the care provided to study subjects

| Effect | Description | Estimate / input |
|---|---|---|
| **Treatment and monitoring covered by contract payments** | The pharmaceutical company funding the trial will pay for the treatment and monitoring provided in clinical trials through contract payments and trial fees. Often, patients participating in a clinical trial receive enhanced disease monitoring, including more follow-up and study visits.<br><br>*The estimates do not consider the possible additional costs for the research hospital for conducting the follow-up, which may arise from the more frequent follow-up/monitoring in the trial compared to regular care. Although the sponsors cover all costs of potentially intensified monitoring, the average production costs of follow-up/monitoring may be higher for the study participants than in normal clinical practice.* | Average annual contract payments to Finnish hospitals from 2018 to 2023:<br>€9,840 / study subject in an ongoing trial [1] |
| **Drugs paid by the study sponsors** | Medicines received by patients participating in clinical drug trials are paid for by the company funding the trial. In practice, this conservatively includes only priced drugs already on the market; no estimates are available for the value of new, unpriced drugs.<br><br>*It is possible that the value of these excluded, unpriced drugs would actually be greater than the total value of the priced drugs included in the analyses here.* | Average annual value of the drugs paid by the study sponsors in Finnish hospitals from 2018 to 2023:<br>€12,023 / study subject in an ongoing trial [2] |
| **Health benefits for the study subjects** | Patients participating in the trials receive novel treatments that are not available for patients outside the trial. | The average gain in quality-adjusted life-years (QALY) is modelled at 0.49 QALYs / study subject in an ongoing trial. [2]<br><br>For novel trial treatments, the willingness-to-pay (WTP), and the value of one QALY, was modelled at €49,940 / QALY. [3] |

1) Survey to Hospitals in spring 2024.
2) Cohen et al. 2019. https://www.healthaffairs.org/do/10.1377/forefront.20190827.553404.
3) Realistic willingness-to-pay (WTP) level based on the threshold used by NICE (£20,000 / QALY), converted to the Finnish level by adjusting for purchasing power parity and typical Finnish willingness-to-pay (x2). There is no established or generally accepted universal WTP threshold for quality-adjusted life-years (QALYs) in Finland, but for instance, Fimea has proposed that €68,000 / QALY is at the upper limit of acceptability in the treatment of colorectal cancer.

# Modelled effects and value drivers – Benefits obtained elsewhere in healthcare

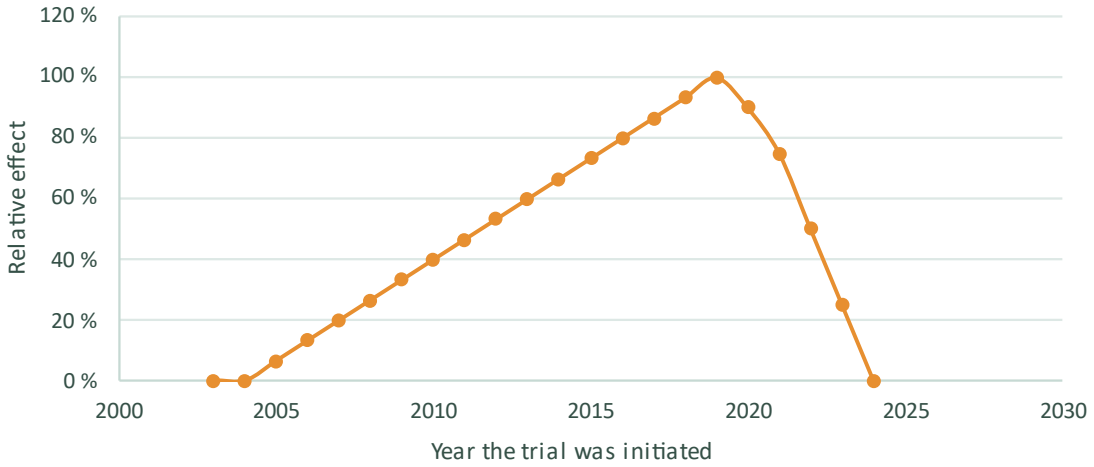
| Effect | Description | Estimate / input |
|---|---|---|
| **Cost benefits elsewhere in healthcare** | Modern medicines can free a significant amount of other healthcare capacity [1]. Under a fixed budget, the drugs paid for by the pharmaceutical companies sponsoring the trial affect not only the patients in the trial, but the treatment of other patients as well. | Value of drugs paid by the study sponsors * 2 * 1.504. [1]<br><br>*The value of drugs very conservatively only includes the priced drug, whose value may possibly be even less than half of the total value of drugs provided by the study sponsors.* |
| **Health benefits elsewhere in healthcare** | Clinical research and the knowledge and experience gained by the research personnel and the research unit have a positive impact on the treatment outcomes and quality of life of all patients treated in the hospital. Based on the survey to Finnish hospitals, the overall impact of clinical drug trials on the quality of life (15D) of patients treated in hospitals conducting a clinical trial averaged approximately 0.0211–0.0468. [2]<br><br>The estimated effect was allocated to a single clinical trial by conservatively modelling the relative impact of a single trial. One study is modelled to impact the treatment of patients in hospitals conducting research effectively for approximately 10.4 years over a 20-year period. Based on this modelling approach, the above-mentioned estimated effect of 0.0211-0.0468 on patients' 15D would have been generated by 1648 clinical drug trials conducted in Finland over the past 20 years. | The model uses the most conservative estimate, assuming that the 'don't know' answer means that the clinical trials do not affect the quality of life of patients treated in that hospital. One trial is modelled to increase the QALY accumulation of one specialised healthcare patient treated in a research-conducting hospital by an average of 0.000133 (= 0.0211 / 1648 * 10.4).[3]<br><br>For the health benefits elsewhere in healthcare, the willingness-to-pay (WTP) threshold was modelled at €29,997 / QALY. [4] |

1) Lichtenberg has estimated that without the drugs that came to market after 1981, on average, the number of hospital days would have been 163 % higher and the number of inpatient care episodes 91 % higher in 15 OECD countries than they were in 2015. (Lichtenberg 2019, https://doi.org/10.1515/fhep-2018-0009). According to Lichtenberg, the reduction in inpatient costs (cost offset) in these OECD countries in 2015 was on average 5.3 times and in Finland 6.76 times the costs spent on these medicines. Considering that at the time of the review, the price of these medicines is about 22.3% of the price when they entered the market (Lichtenberg 2023, https://doi.org/10.1016/j.jval.2023.08.011), the corrected multiplier for a new medicine is 1.504 (=6.76*0.223). Lichtenberg has also previously estimated that the reduction in inpatient care costs corresponds to about half of the total reduction in healthcare costs caused by new medicines, meaning the total cost reduction is 2*1.504 = 3.008 times the current price of the medicines. (Lichtenberg 2014, https://www.journals.uchicago.edu/doi/10.1086/679110).
2) Survey to Finnish hospitals in spring 2024. The average impacts on patients' quality of life reported by the responding hospitals were converted to 15D-values based on the literature (Alanne et al. 2015, https://doi.org/10.1007/s11136-014-0787-4). The estimated impact on the patients treated in a hospital is similar to that modelled in previous studies (Väätäinen et al. 2023, https://doi.org/10.1016/j.jval.2023.09.562).
3) Based on the survey to Finnish hospitals (2024), 5 university hospitals and 4 central hospitals conduct clinical drug trials in Finland. In 2022, a total of 1,810,028 specialised healthcare patients were treated in the catchment areas these hospitals serve (at the time, named hospital district), representing approximately 74 % of all specialised healthcare patients in Finland in 2022 (N=2,459,880; (https://sampo.thl.fi/pivot/prod/fi/thil).
4) Realistic willingness-to-pay (WTP) level based on a British study (Claxton et al. 2015 https://doi.org/10.3310/hta19140), converted to the Finnish level by adjusting for purchasing power parity and typical Finnish willingness-to-pay (x2). There is no established or generally accepted universal WTP threshold for quality-adjusted life-years (QALYs) in Finland, but for instance, Fimea has proposed that €68,000 / QALY is at the upper limit of acceptability in the treatment of colorectal cancer.

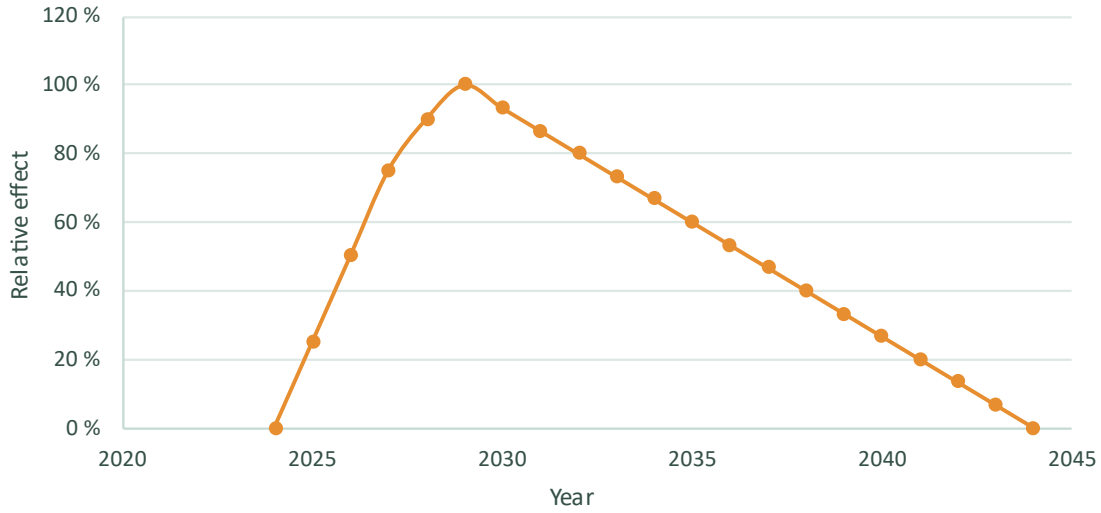
# Modelled relative effect of a clinical drug trial on the treatment and quality of life of specialised healthcare patients

The effect of an individual trial is modelled to accumulate over the course of the trial (3.35 years on average) and on average for approximately one year after the trial concludes, as the knowledge observations gained are integrated into clinical practice. After this, the effect of research on healthcare and clinical practice diminishes as knowledge and practices become outdated with the influx of new knowledge from ongoing research and evolving practices. Modelled in this way, a single clinical trial effectively influences healthcare for an average of 10.4 years within a 20-year period.

**Relative effects of the trials initiated from 2003 to 2024 on the treatment and quality of life of specialised healthcare patients in 2024, according to the trial initiation year**




**Relative effect of a trial initiated in 2024 on the treatment and quality life of specialised healthcare patients**



# Considering the limitations and scope of the evaluation, it may be appropriate or useful in future studies to:

- Examine and model the societal value associated with vaccine research. Vaccine trials differ from other clinical drug trials, and their value is formed differently than in research examining treatments of pre-existing conditions.
- Examine the societal value of clinical research across different therapeutic areas. This evaluation modelled the total value at the national level in Finland and at the level of an average clinical drug trial. However, the value associated with clinical drug trials is likely to vary significantly between therapeutic areas, due to differences in typical treatment and drug costs, as well as patient numbers across various diseases.
- Examine more closely the societal value associated with clinical trials in different future scenarios, or how much, for example, the public sector should potentially invest in supporting clinical drug research.
- Evaluate the societal value produced by academic and investigator-initiated drug trials and examine the key value drivers in these perspectives. About one-quarter of the clinical drug trials conducted in Finland are academic or investigator-initiated.
- Consider the opportunities for Finnish institutions to conduct more efficient and effective clinical research, such as the possibility of recalling biobank sample donors based on pre-profiling to assess their inclusion in clinical trials.[1,2]

1) ISPOR - Value Assessment Modelling of Fingenious® Recall Service for Clinical Trials
2) Value assessment modelling of Fingenious recall service for clinical trials (youtube.com)

# Contact information


**Principal investigator**

Saku Väätäinen

Senior Consultant

saku.vaatainen@esior.fi

050 5999 604

**sakuvaatainen**

**Contracts and collaboration**

Erkki Soini

CEO, Health economist

erkki.soini@esior.fi

0400 533 971

**erkkisoini**


ESIOR

*Creating Insights*

ESIOR

# Creating Insights

- **Kuopio-based, award-winning global player in health economics since 2006.**
- **Our services**
  - SHEOR: High-quality social and health economics services
  - DSEG: Data science and evidence supporting your products
  - SPESiOR®: The first private secure processing environment (SPE)
  - Market Access: Your partner in market entry
- **Our strengths**
  - Highest level of expertise
  - Strong scientific background, award-winning works, hundreds of peer-reviewed scientific references, hundreds of other references
  - Solid experience in authority and stakeholder communication
  - Wide network of stakeholders, connection to every corner of the health and social care industry
- **Our clients**
  - Private: Pharmaceutical companies, device manufacturers, IT companies,
  - Public: All stakeholders in social welfare and healthcare, including hospitals, wellbeing service counties, counties, and research institutions.
- www.esior.fi newsletter, blog, contact, and much more.

## Data

Gain insight into your competitive advantage

## Analysis

Demonstrate your competitive advantage

## Knowledge management

Transform insights into action and competitive advantage

## Communication

Make a difference with effective communication