IPHA Clinical Trials Activity Comparison Report 2024

Irish Pharmaceutical Healthcare Association

22nd January 2024

I. Introduction

This year's analysis looks at how the level of clinical research activity in Ireland compares with two other European countries that are comparable in terms of population and economic wealth; Finland and Denmark. The US database, www.clinicaltrials.gov, was used as the main data resource. It is provided by the U.S National Library of Medicine and contains details of privately and publicly funded clinical trials conducted worldwide. Additionally, the EudraCT database and HPRA Annual Reports were analysed to obtain further information on the trends in the clinical trial landscape in Ireland.

II. Objectives

- To evaluate the number of IPHA-member sponsored clinical trials conducted in Ireland compared to all-industry sponsored clinical trials from 2014 to 2023.
- To determine the therapeutic areas that have the most industry sponsored clinical trials, in Ireland.
- To compare the number of clinical trials in Ireland with those in Denmark and Finland over a 10-year period using both clinicaltrials.gov and EudraCT database.

III. Methods

(a) Using www.clinicaltrials.gov, data from 01.01.14 to 31.12.23 was analysed, with information downloaded on 19.01.24. Each country was filtered for the following.

- Study type: Interventional clinical trials
- Study phase: Phase 1 – Phase 4
- Funder type: Industry
- Status: Recruiting, Active and Completed

(b) Using EudraCT database, data was filtered by date range from 01.01.14 to 31.12.23, with information downloaded on 21.01.24. Each country was filtered for the following.

- Study type: Interventional clinical trials
- Study phase: Phase 1 – Phase 4
- Status: Ongoing and Completed

The EudraCT database does not contain a search function to filter industry only. This resulted in higher number of clinical trials associated with all three countries.

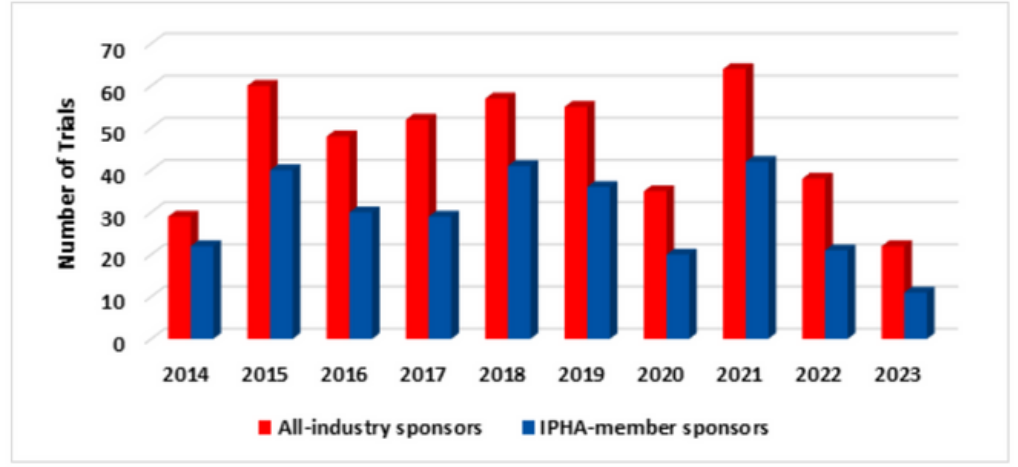
Since 31.01.23, new clinical trial applications in the EU/EEA must be submitted through the Clinical Trials Information System (CTIS). Earlier applications submitted through the EU Clinical Trial Register, can still be viewed through the EudraCT database. Furthermore, if the clinical trial completion date is after 30.01.25, any ongoing trials need to be transferred to CTIS. However, for the purpose of our analysis, we examined the EudraCT rather than CTIS due to the date range analysed.

IV. Results

(a) IPHA-member sponsored clinical trials in comparison to all-industry sponsored clinical trials

IPHA-member companies performed the majority of all-industry sponsored interventional clinical trials in Ireland from 2014 to 2023. IPHA members companies sponsored or collaborated in 292 clinical trials over this period, accounting for 63% out of the 460 listed all-industry sponsored interventional clinical trials. Figure 1 illustrates the breakdown by year of IPHA-member sponsored clinical trials in comparison to all-industry sponsored clinical trials in Ireland. There is a decrease of over 40% in the number of all-industry sponsored clinical trials taking place in 2022 compared to 2021, and a similar trajectory is evident for 2023.

Figure 1: IPHA-member sponsored clinical trials in comparison to all-industry sponsored clinical trials



(b) HPRA – Clinical Trials Authorisations (2021 – 2022)

Analysis of the HPRA Annual Reports showed that in 2021 there were 107 applications authorised for clinical trials of human medicine under the EU Clinical Trials Directive. In 2022, this figure reduced to 64 clinical trials authorised under the EU Clinical Trials Directive and three authorisations under the new EU Clinical Trials Regulation. From 2021 to 2022 there was a 37% decrease in applications authorised by the HPRA. This may tie in with the lower numbers of all-industry sponsored clinical trials that were examined in 2022 (Figure 1).

(c) IPHA-member sponsored clinical trials split into their phases

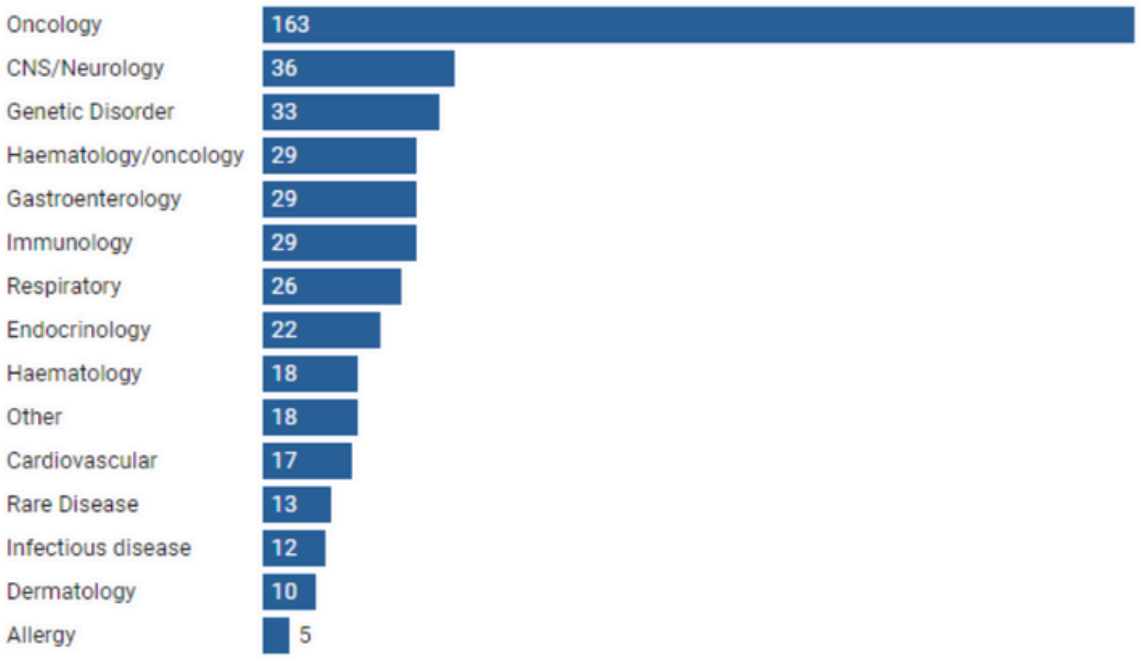
The data from the 292 IPHA-member sponsored clinical trials in Ireland were divided into their phase status. Nearly three-quarters of IPHA-member sponsored clinical trials took place during Phase III (73%), followed by Phase II (17%) shown in Figure 2.

Figure 2: IPHA-member sponsored clinical trials by phase

(d) All-industry sponsored clinical trials divided into their therapeutic areas

The majority of clinical trials that took place were in oncology (n=192) which included blood cancers. This represented 42% of all industry-sponsored clinical trials (n=460). Neurology, gastroenterology, immunology and respiratory, combined, represented just over a quarter of clinical trials carried out during 2014 to 2023, illustrated i Figure 3.

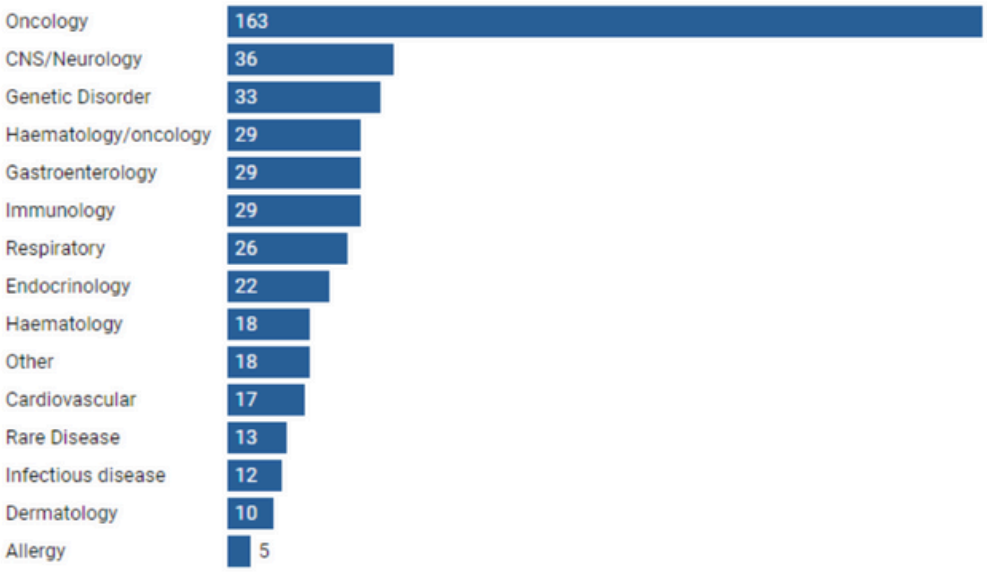
Figure 3: All-industry sponsored clinical trials by therapeutic area



(e) IPHA-member sponsored clinical trials divided into their therapeutic areas

Oncology including blood cancer trials (n=147) made up half of the IPHA-member sponsored clinical trials (n=292) that were conducted in this time period. Gastroenterology, immunology and endocrinology accounted for 21% of clinical trials, Figure 4.

Figure 4: IPHA-member sponsored clinical trials by therapeutic area



(f) Ireland in comparison to Denmark and Finland using www.clinicaltrials.gov

For all three countries the majority of clinical trials were Phase 3. Out of 460 clinical trials that took place in Ireland, 311 (68%) were Phase 3 and 97 (21%) Phase 2. Out of 1290 clinical trials that occurred in Denmark, 675 (52%) were phase 3 and 333 (26%) Phase 2. Finland had 661 clinical trials, with 390 (59%) Phase 3 and 130 (20%) Phase 2, Figure 5.

Figure 5: Phases of clinical trials identified by country between 01/01/2014 and 31/12/2023

Figure 6: Number of clinical trials year on year using www.clinicaltrials.gov

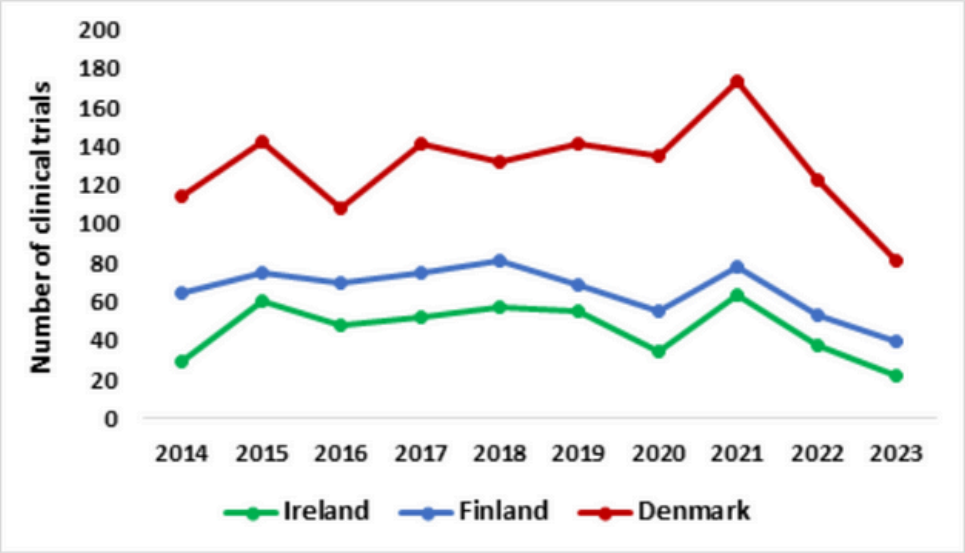
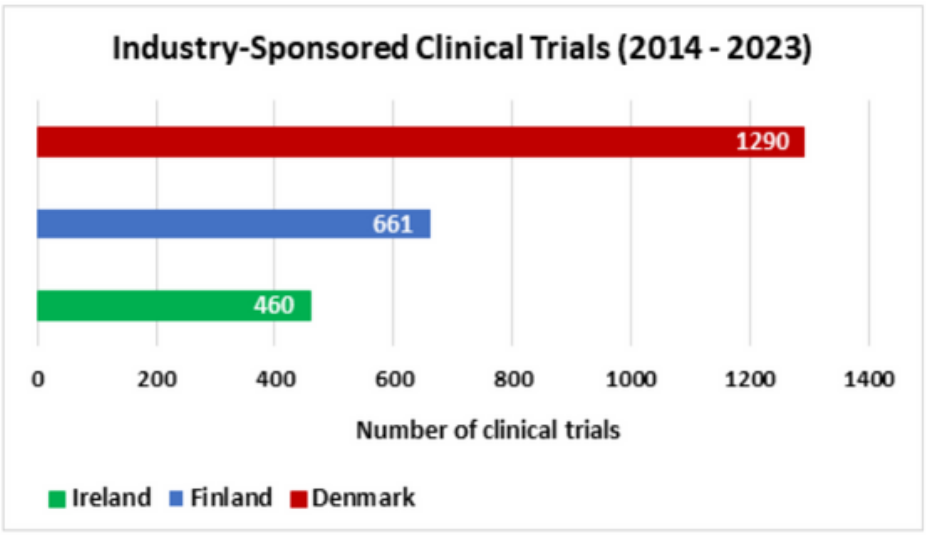


Figure 6 categorises clinical trials by the year in which the clinical trial began. The data indicates that from 2021 to 2023 there was a decline in the number of clinical trials for each of the three countries analysed by between 49% and 66%.

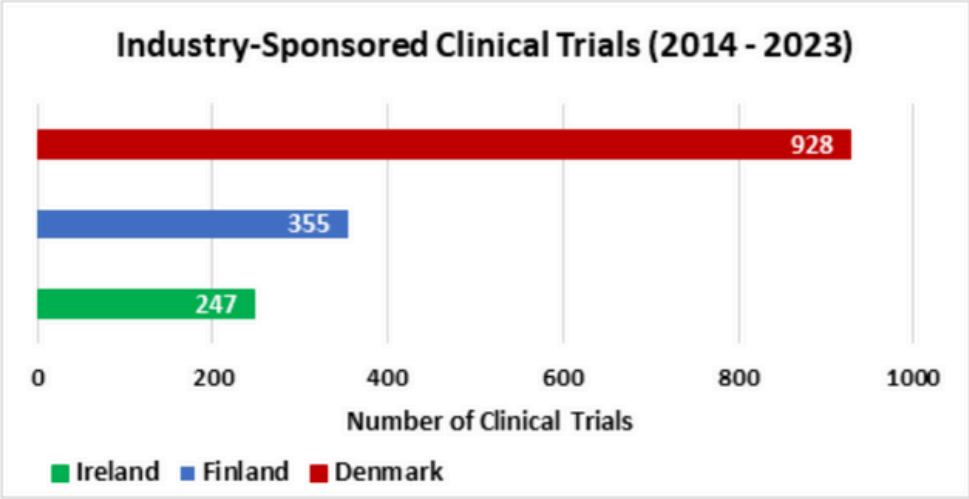
Ireland attracted fewer industry-sponsored interventional clinical trials than both Finland and Denmark between 2014 and 2023 (Figure 7), despite all three countries having a similar population size and economic wealth (Figure 10). Denmark had nearly three times as many clinical trials when compared to Ireland. Just to note 881 clinical trials viewed in figure 7 took place in all three countries (Ireland, Finland and Denmark) or at least two countries.

Figure 7: Comparison of number of Industry-sponsored interventional clinical trials by country



There were 1530 clinical trials that took place in either Ireland, Finland or Denmark. These clinical trials also had other locations worldwide. Out of 1530 clinical trials carried out, 247 (16%) were conducted in Ireland compared to 355 (23%) in Finland and 928 (61%) in Denmark, Figure 8. This analysis removed any industry-sponsored clinical trials that had site locations in all three countries (Ireland, Denmark and Finland) or in at least two. So, for example, the 247 clinical trials that took place in Ireland, there were no site locations in either Denmark or Finland.

Figure 8: Comparison of number of Industry-sponsored interventional clinical trials by country



Ireland in comparison to Denmark and Finland using EudraCT database

This analysis does not breakdown the sponsor type into industry only, therefore, there were higher number of interventional clinical trials associated to all three countries. Figure 9 shows a similar trend to that of Figure 7, with Denmark having over three times more clinical trials taking place.

Figure 9: Comparison of number of interventional clinical trials by country

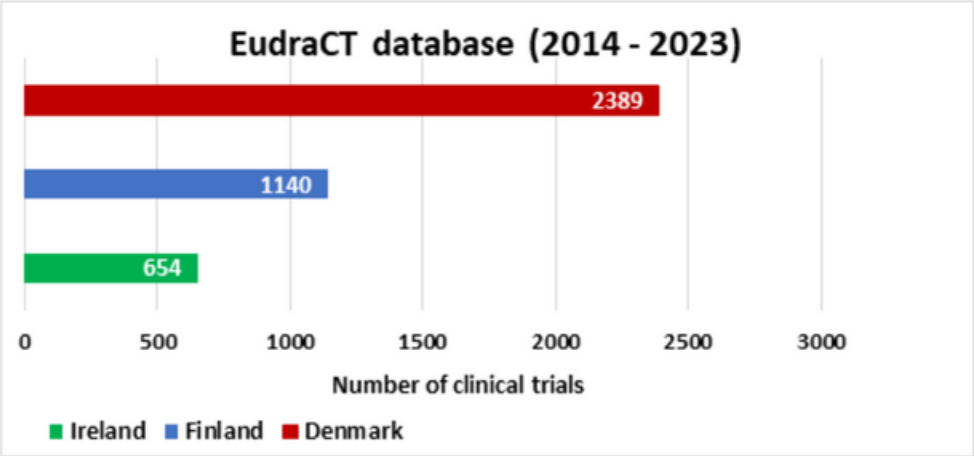
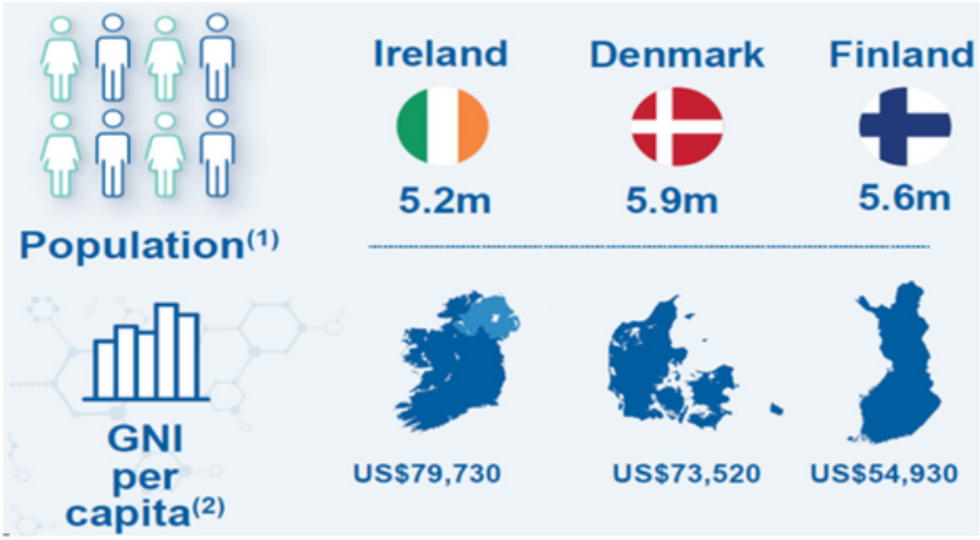


Figure 10: Infographic on population and economic wealth amongst the three countries

(source: Eurostat (1) and the world bank (2))



Conclusion

Whether we look at the US or EU database, both show the same pattern, with Finland obtaining more clinical trials than Ireland. Both databases also show that Denmark has three times more clinical trials compared to Ireland.
This analysis shows we are lagging behind certain European countries with similar populations and economic performances. Ireland should be attracting more clinical trials, especially with the scale of the biopharmaceutical industry's manufacturing footprint.

IPHA has urged reforms in the clinical trials process to help accelerate new medicines development and raise standards of care. These five steps should help.

1. Standardise clinical trial start-up requirements (including Data Protection Impact Assessments) and timelines for hospitals;
2. Designate specific clinical trial signatories in each hospital with a standard sign-off process;
3. Appoint one permanent clinical research nurse post for each teaching hospital;
4. Ring-fence clinical trial funding and working time for multidisciplinary research; and,
5. Protect dedicated research time.