

The Swedish Drug Development Pipeline

May 2011

A survey conducted by:



The survey

- In February – March 2011 a survey of the Swedish Drug Development Pipeline was conducted by SwedenBIO in cooperation with Invest Sweden and VINNOVA.
- The survey includes projects originating and developed in Sweden*.
- SwedenBIO, Invest Sweden and VINNOVA will use the results to promote the Swedish Drug Development industry and to generate business contacts.
- An overview of projects originating from AstraZeneca as well as an overview of clinical trials performed in Sweden are summarized in the Appendices.
- SwedenBIO, Invest Sweden and VINNOVA would like to thank all the participating companies.

*The analysis only includes companies that conduct research in Sweden.

Summary

- The number of projects in phases I–III has decreased with 10 projects (14 %) since previous year (63 projects 2011 and 73 projects 2010).
- The number of companies with projects in phases I-III was slightly decreased, from 38 companies 2010 to 35 companies 2011.
- Three projects successfully exited phase III during 2010.
- Cancer is the therapeutic area with most projects.
- There has been a continuous increase in number of projects with biologics in phase III since 2007
- Half of the projects in phase I-III originates from internal research

Appendix

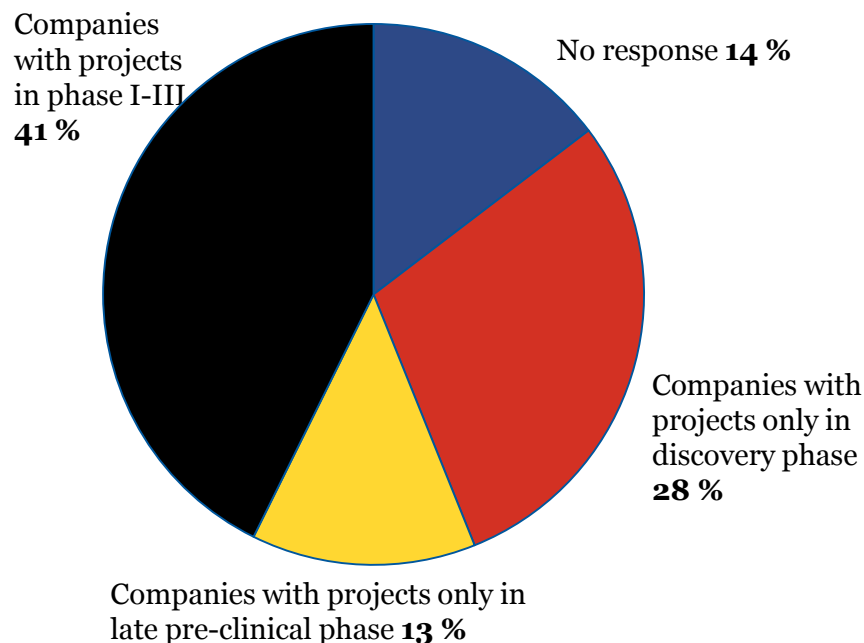
A, Globally, AstraZeneca has 13 more projects in their pipeline than the combined pipeline of the Swedish Drug Development companies.

B, Just as previous years, Sweden is among the top ten countries in number of clinical trials performed.

Survey details

85 companies were asked and 73 responded

Response to the survey*



- 85 companies¹ were contacted about participating in the survey and 87 % of them responded.
- 24 companies (28 %) stated that they only had projects in discovery phase.
- 12 companies (14 %) did not reply.
- 11 companies (13 %) has products only in late pre-clinical phases
- In this presentation, only companies with projects in clinical trials (CT) have been included in the statistics (35 for 2011, 38 for 2010, 33 for 2009, 34 for 2008, 30 for 2007 and 24 for 2006).

Source: Interviews, SwedenBIO/VINNOVA//InvestSweden analysis -11

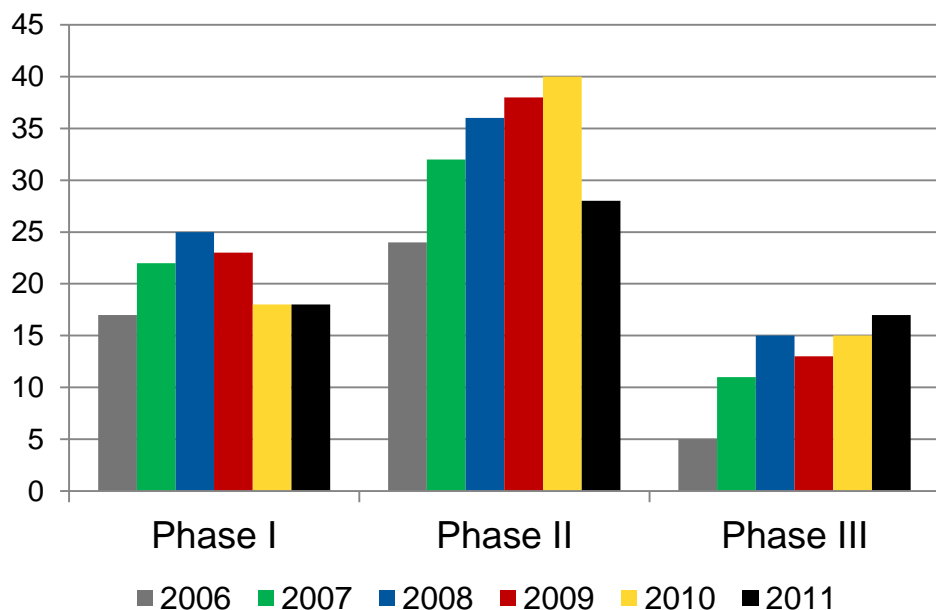
*Note: AstraZeneca is not included in this graph

¹ Selected with regard to potentially relevant projects originated and developed in Sweden

Overview

There is a 30 % decrease of number of projects in phase II since last year

Swedish Drug Development pipeline* in clinical phases



Source: SwedenBIO/VINNOVA/InvestSweden analysis -06, -07, -08, -09, -10 and -11

* Note: AstraZeneca is not included in this graph

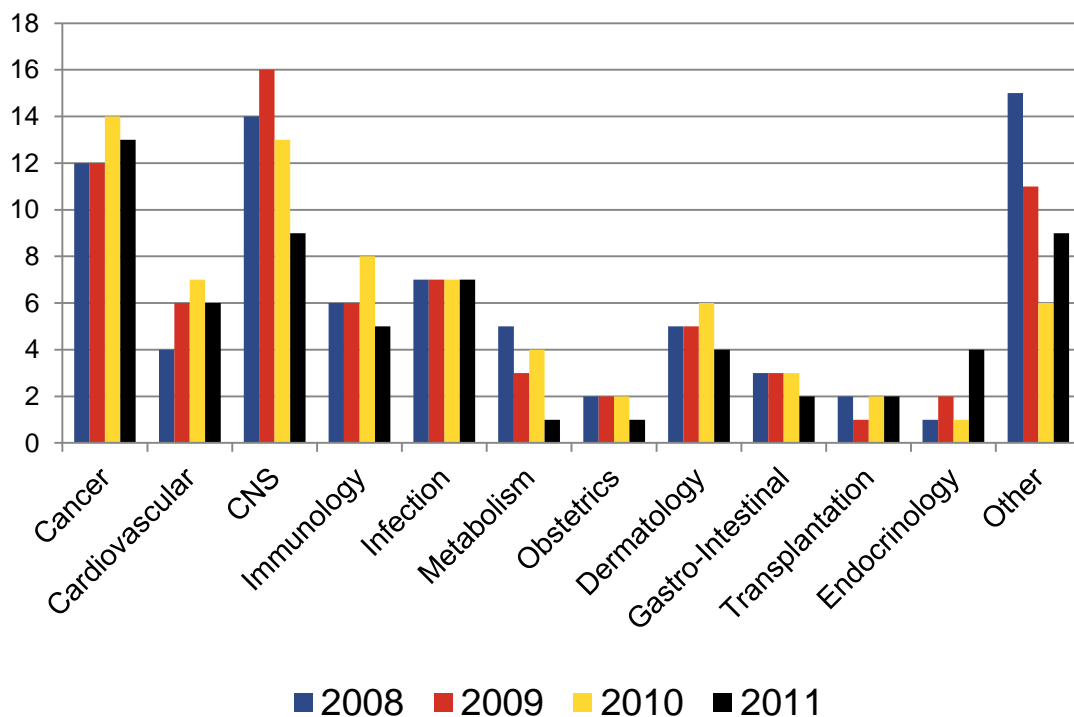
• Comparison to last years' analysis:

- In total there are 63 projects in clinical phases I-III 2011, which is a decrease with 10 project from 2010 (63 for 2011, 73 for 2010, 74 for 2009, 76 for 2008, 65 for 2007 and 46 for 2006).
- In total, 12 fewer projects were reported for phase II this year and that is reflected in the decrease of the total number of projects.
- There is a slight increase in projects in phase III, with 17 projects for 2011 (15 for 2010, 13 for 2009 and 15 for 2008)
- The number of projects in phase I continues to be low.

Comparison by therapeutic area in phases I–III

The pipeline of the Swedish drug discovery companies is still strong and diverse

Number of projects in phases I-III by therapeutic area



- Cancer is the therapeutic area with most projects.
- There is a decrease by four projects in the therapeutic area CNS. The decrease is mainly in phase II and none of the projects have gone into phase III.
- The category “other” include projects in e.g. pain, osteoporosis and with unknown therapeutic area.

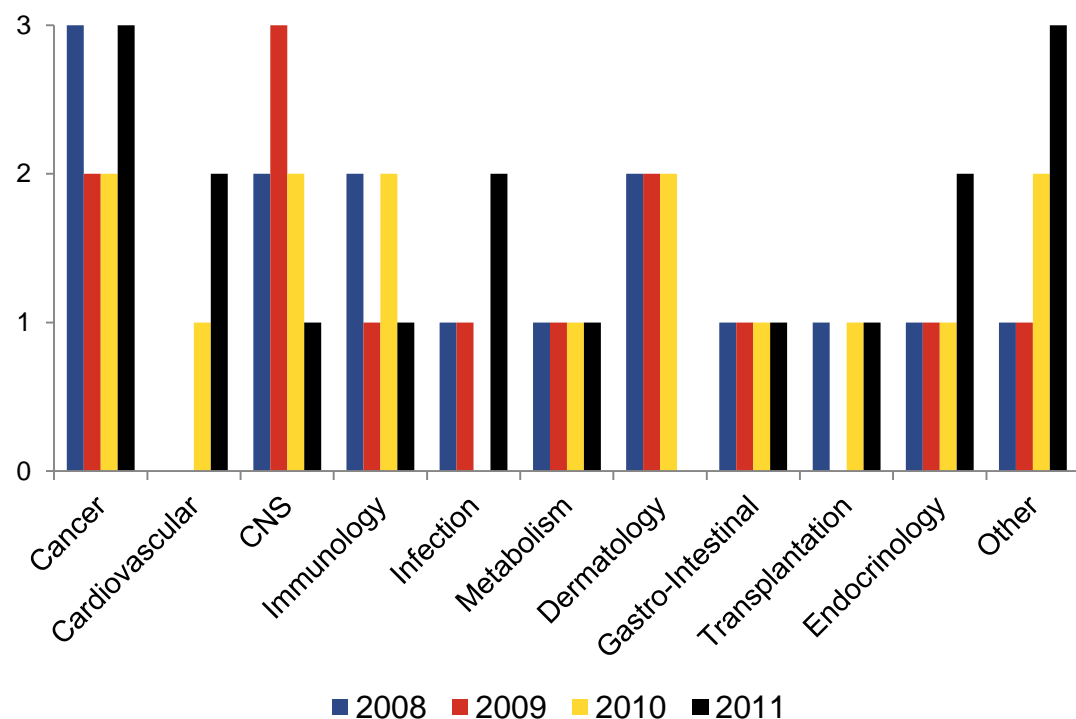
Source: SwedenBIO/VINNOVA/InvestSweden analysis --08, -09, -10 and -11

* Note: AstraZeneca is not included in this graph

Comparison phase III by therapeutic area

Three projects have exited phase III with positive results

Projects in phase III by therapeutic area



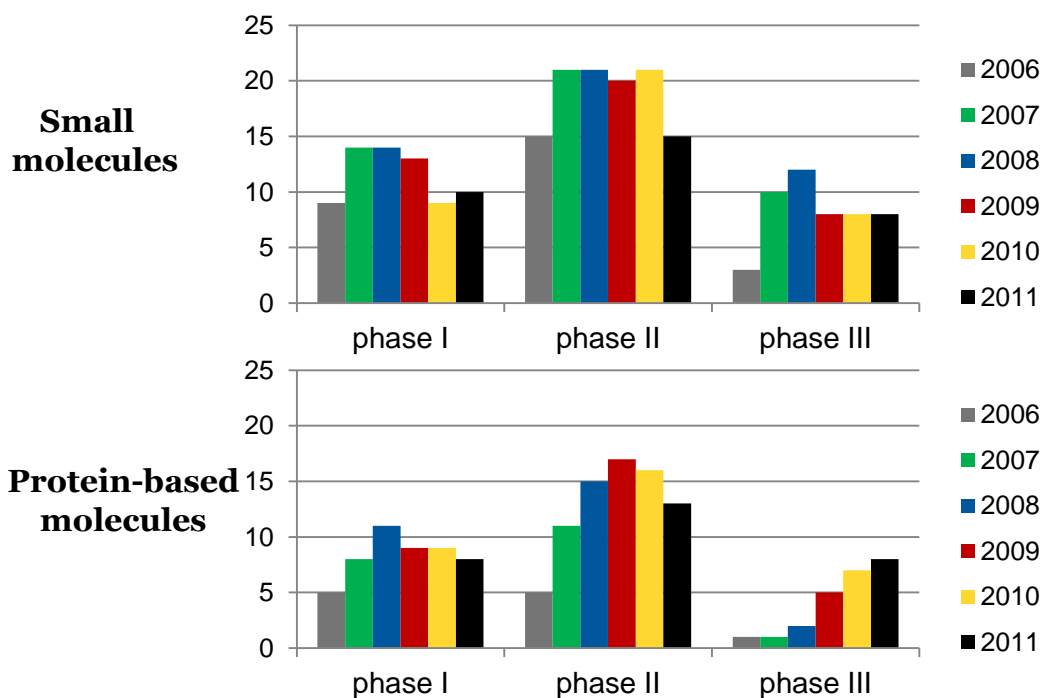
- One project within the therapeutic area CNS and two within Dermatology exited phase III with positive results. Abstral was approved in both USA and Canada during 2010. Emtrix/NaloxTM and Kaprolac[®] were launched during 2010.
- Two of the projects in the category Other are within blood disorders.
- One of the projects Infection has progressed from phase II since last year. The other project was categorized under Other last year.
- The majority of projects reported to be in phase III previous years remain there.

Source: SwedenBIO/VINNOVA/InvestSweden analysis --08, -09, -10 and -11

* Note: AstraZeneca is not included in this graph

Distribution of small and large molecules

Biologics as popular as small molecules



- Out of the 63 projects in phases I–III 2011, 33 are small molecules, 29 are protein-based molecules and 1 was not disclosed in the survey.
- Projects with protein-based molecules continue to increase in phase III.

Source: SwedenBIO/VINNOVA/InvestSweden analysis -06, -07, -08, -09, -10 and -11

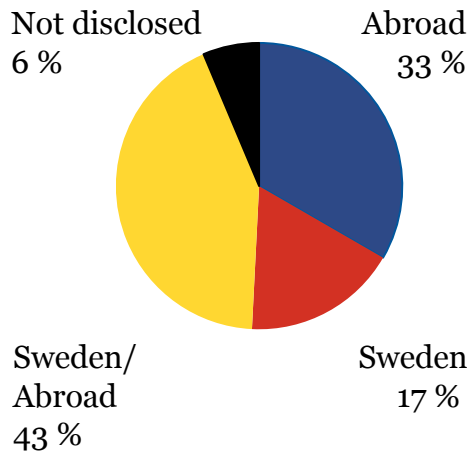
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Location of Clinical Trials

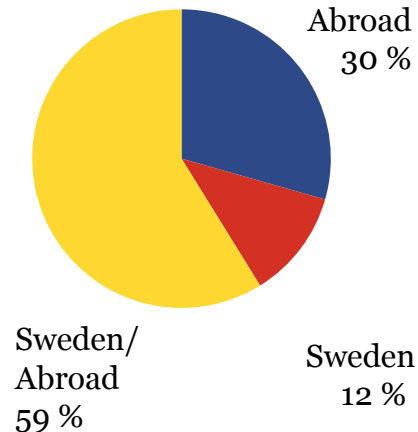
Swedish patients will be included in 12 of 17 phase III projects

Location of Clinical Trials

Phases I-III



Phase III



- Swedish patients are included in a majority of the projects in phases I–III.
- Of the 17 projects in phase III, 10 are tested in clinics both in Sweden and abroad, 5 abroad and 2 in Sweden.
- Of the projects in phases I–III, a minority are tested in Sweden alone.

Source: SwedenBIO/VINNOVA/InvestSweden analysis 2011

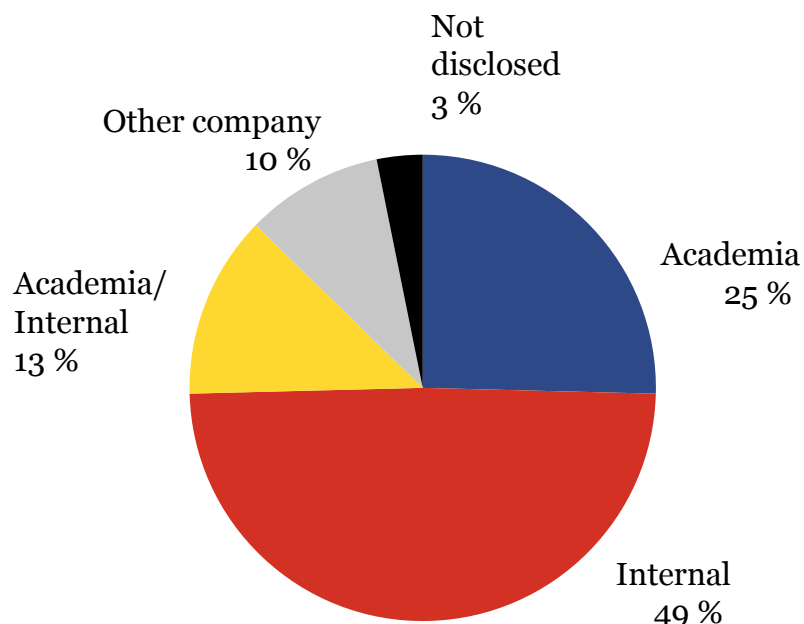
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Origin of project

Projects increasingly originate from research within companies

Origin of project

Phases I–III



- This year almost half of the projects originate from research within the company, which is an increase by 60 % from previous year.
- One project out of ten are acquired from another company, this is decrease by 50 % from previous year's report.
- Academia is still an important contributor to Swedish drug discovery, with two out of every five projects originating from cooperation with academia.

Source: SwedenBIO/VINNOVA/InvestSweden analysis 2011

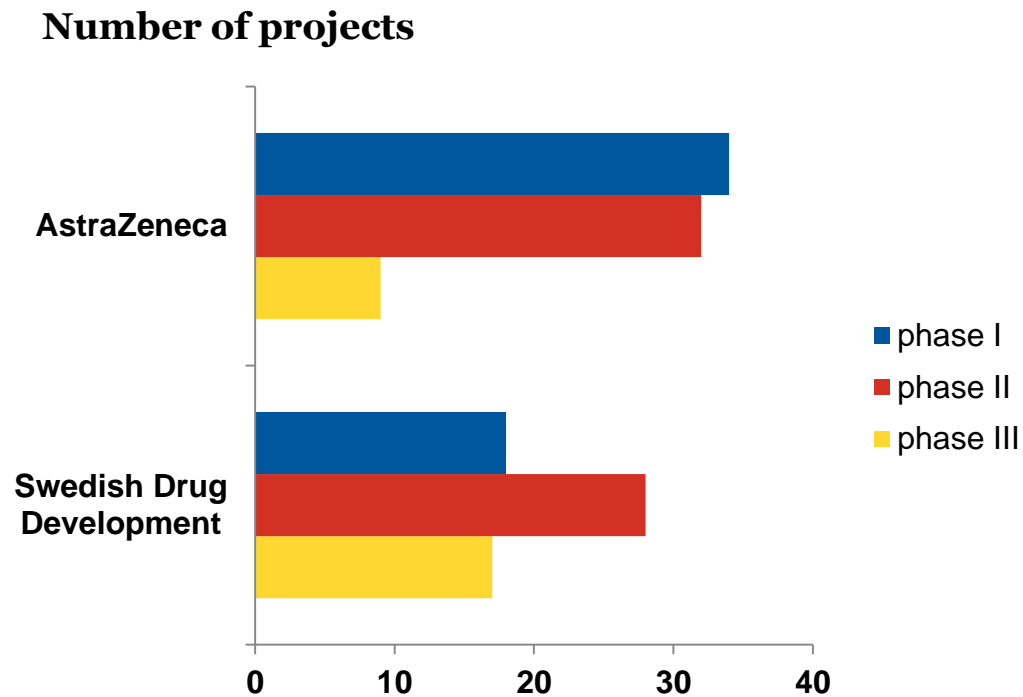
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Conclusion

- The Swedish Drug Discovery Pipeline has fewer projects 2011, than previous years. An analysis of the data shows that out of the 28 reported phase II-projects, 13 projects were the same as previous year, 14 were new projects and 20 were no longer in phase II nor had they moved into phase III.
- Five projects have advanced from phase II to phase III, three projects exited phase III with positive results and three projects exited with negative results or have yet to be approved by the Medical Products Agency (MPA).
- The Swedish Drug Discovery Pipeline is still diverse, with Cancer being the therapeutic area with most projects. CNS and Infection are other popular areas, even though CNS has four fewer projects this year compared to 2010. The decrease is in phase II and none of those projects have advanced into phase III.
- Academia is still an important contributor to Swedish drug discovery companies, but an increasing number of projects are developed internally and now almost half of the projects in the pipeline originates from research within the company.

AstraZeneca versus the Drug Development sector

Globally AstraZeneca has 13 more projects in clinical trials as all of the Swedish Drug Development companies together

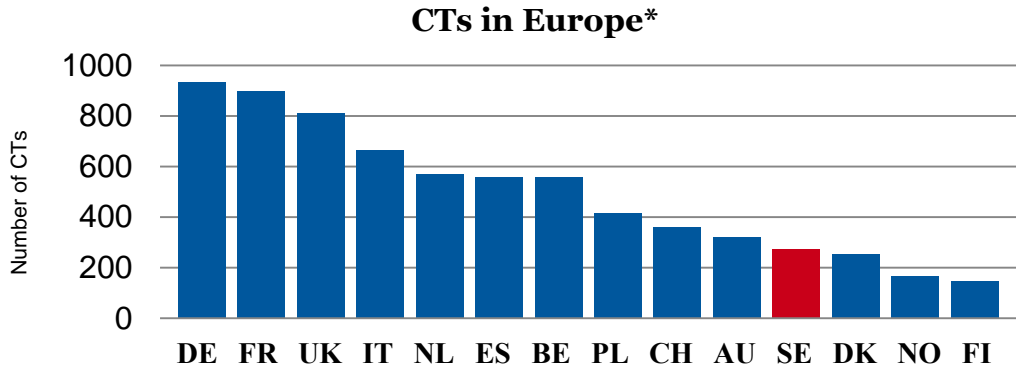


- Globally AstraZeneca has 75 projects in phases I–III.
- Swedish Drug Development companies have 63 projects in total.
- AstraZeneca has an additional 17 products (23 % of the pipeline) in clinical trials that are line extensions.

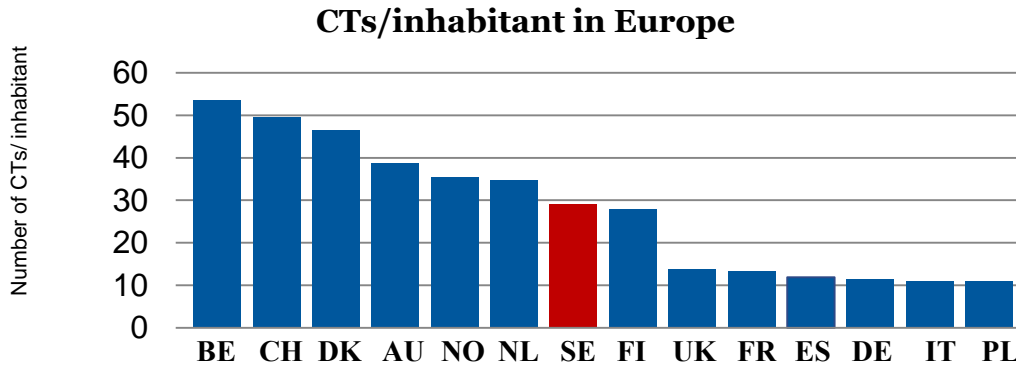
Source: SwedenBIO/VINNOVA/InvestSweden analysis 2011 and AstraZeneca Pipeline 2010
Note: Graph includes only new chemical entities

Clinical Trials in Europe

Sweden is among the top ten countries in number of clinical trials performed



* Active trials



- In February 2011, around 270 of the active trials registered at the website clinicaltrials.gov were from Sweden.
- Sweden is an attractive country for clinical trials, but lags behind the other Scandinavian countries when comparing clinical trials per inhabitant.
- Sweden has a long tradition of performing clinical trials and has a well working infrastructure (hospitals, researchers, Medical Product Agency, biobanks et c).

Source: <http://clinicaltrials.gov>; feb 2011

Note: DE:Germany; UK: United Kingdom; FR: France; IT: Italy; NL: Netherlands; BE: Belgium; ES: Spain; CH: Switzerland; PL: Poland; AU: Austria; DK: Denmark; SE: Sweden; NO: Norway; FI: Finland

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