

The Swedish Drug Development Pipeline

May 2010

A survey conducted by:

The Swedish Life Science Industry Organization
sweden **BIO**



ISA
Invest in Sweden Agency

The survey

- In February – April 2010 a survey of the Swedish Drug Development Pipeline was conducted by SwedenBIO in cooperation with Invest in Sweden Agency (ISA) and VINNOVA.
- The survey includes projects originating and developed in Sweden*.
- SwedenBIO, ISA 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, ISA 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 remained 70+, which is similar to previous years.
- The number of Drug Development companies in phases I-III was slightly increased, from 33 companies 2009 to 38 companies 2010.
- Three products were approved by the Medical Products Agency (MPA) during 2009.
- The majority of projects were found within the therapeutic areas cancer and CNS.
- 51 % of the projects in phases I-III were chemical molecules, 43 % were protein-based and 6 % were not disclosed in the survey.

Appendix

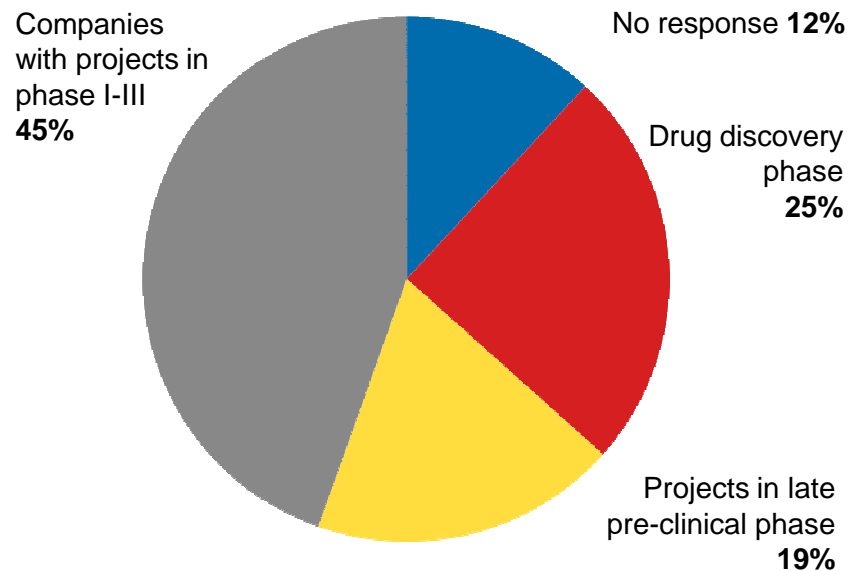
A, Globally, AstraZeneca has 16 more projects in their pipeline than all other Swedish Drug Development companies taken together.

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

Survey details

85 companies were asked and 75 responded

Response to the survey*



Source: Interviews, VINNOVA/SwedenBIO/ISA analysis -10
*Note: AstraZeneca is not included in this graph

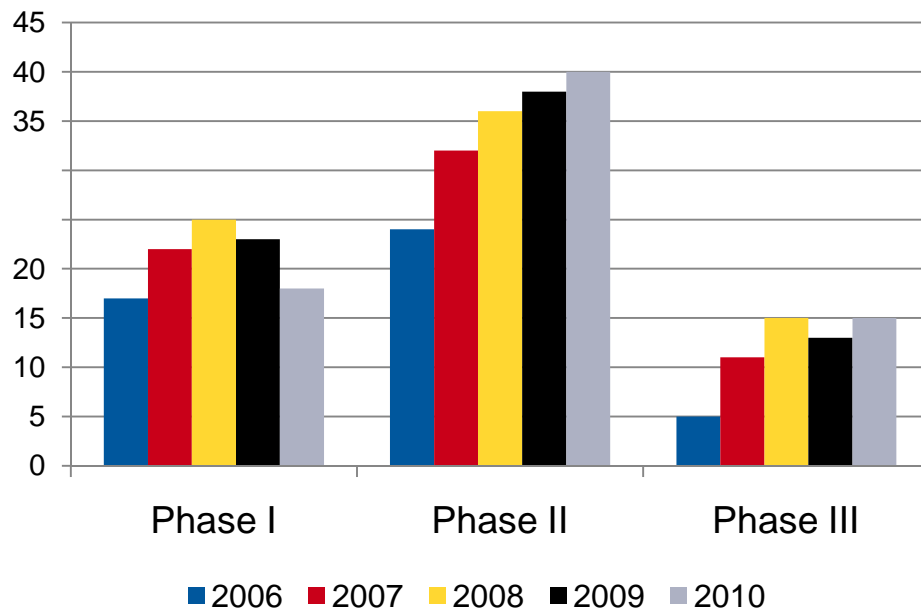
- 85 companies¹ were contacted about participating in the survey.
- 21 companies (25%) stated that they only had projects in discovery phase.
- 10 companies either did not reply or stated that they did not wish to participate because of confidentiality agreements etc.
- 16 companies (19%) has products only in late pre-clinical phases
- In this presentation, only companies with projects in clinical trials (CT) have been included in the statistics (38 for 2010, 33 for 2009, 34 for 2008, 30 for 2007 and 24 for 2006).

¹ Selected with regard to potentially relevant projects

Overview

Three products approved during 2009

Swedish Drug Development pipeline* in clinical phases



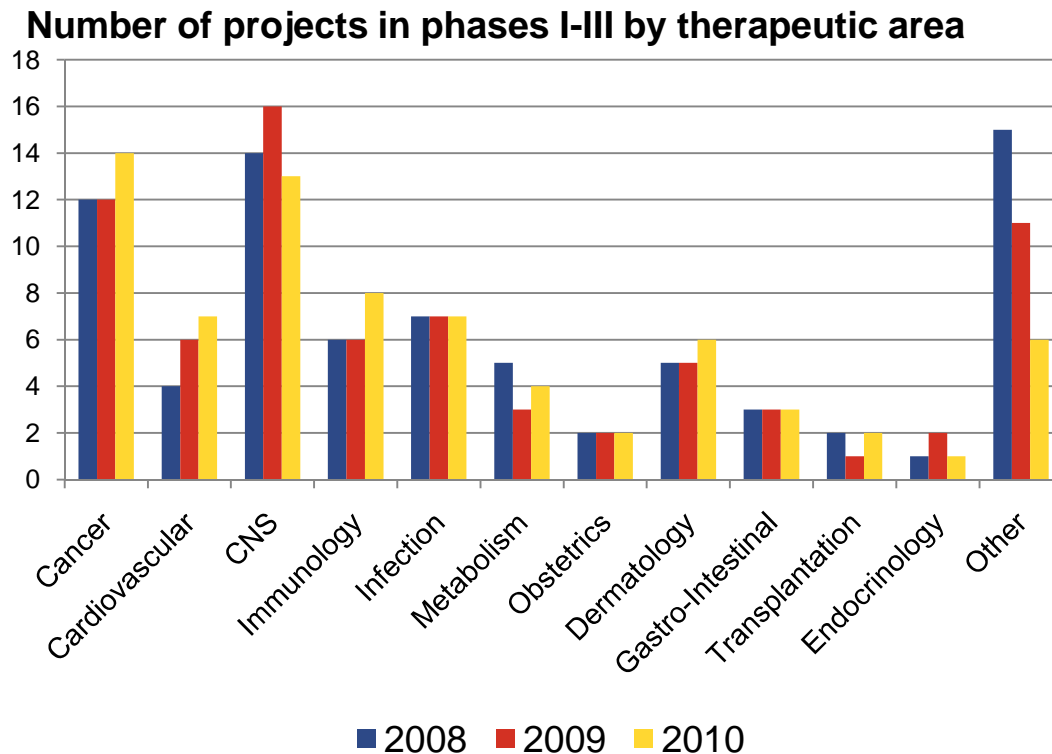
Source: VINNOVA/SwedenBIO/ISA analysis -06, -07, -08, -09 and -10

* Note: AstraZeneca is not included in this graph

- **Three products approved during 2009,** Xerclear, Abstral and Edluar were approved by the Medical Products Agency (MPA) during 2009
- **Comparison to last years' analysis:**
 - In total there are 73 projects in clinical phases I-III 2010, which is a small decrease with one project from 2009.
 - The number of projects in phase I has decreased the last three years from 25 projects in 2008 to 18 projects 2010. In contrast the number of projects in phase II has steadily increased since 2006.
 - The number of projects in phase III remains constant with around 15 projects from 2008 to 2010.
 - There are two additional projects in phase II that are line extensions.

Comparison by therapeutic area in phases I–III

Projects within therapeutic areas cancer and CNS are dominating the pipeline



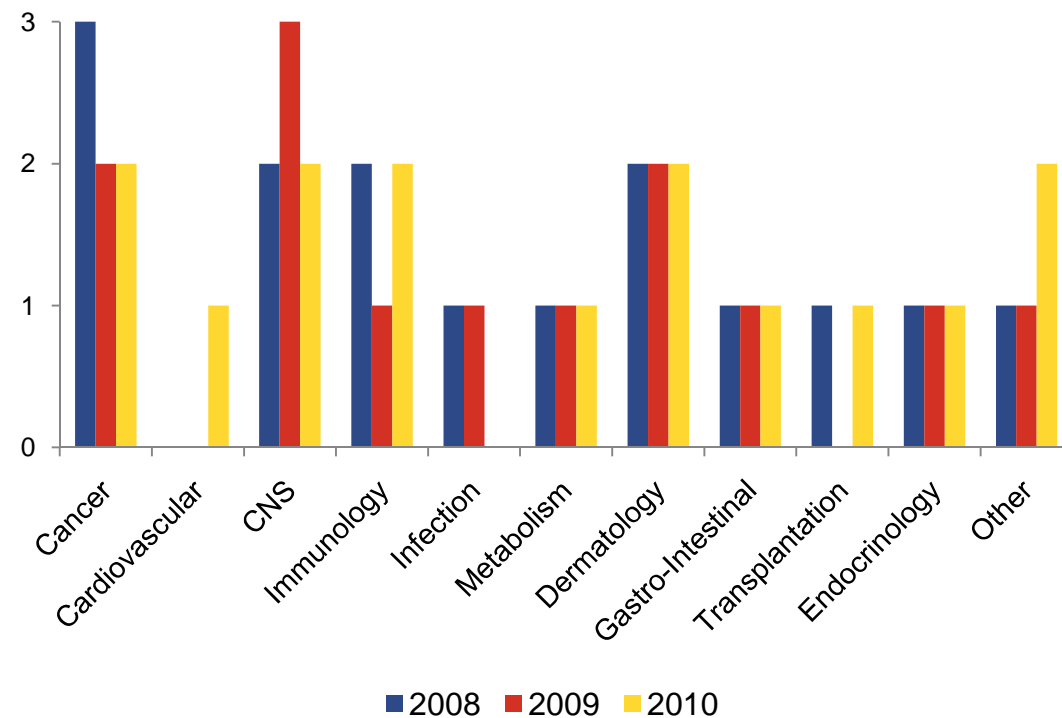
Source: VINNOVA/SwedenBIO/ISA/analysis -08, -09 and -10
Note: AstraZeneca products are not included in this graph

- Cancer and CNS are the therapeutic areas with most projects.
- There is a slight increase in number of projects in the areas cancer, cardiovascular, immunology, metabolism and dermatology.
- The category “other” include projects with unknown therapeutic area.

Comparison phase III by therapeutic area

Two projects have exited phase III with positive results

Projects in phase III by therapeutic area

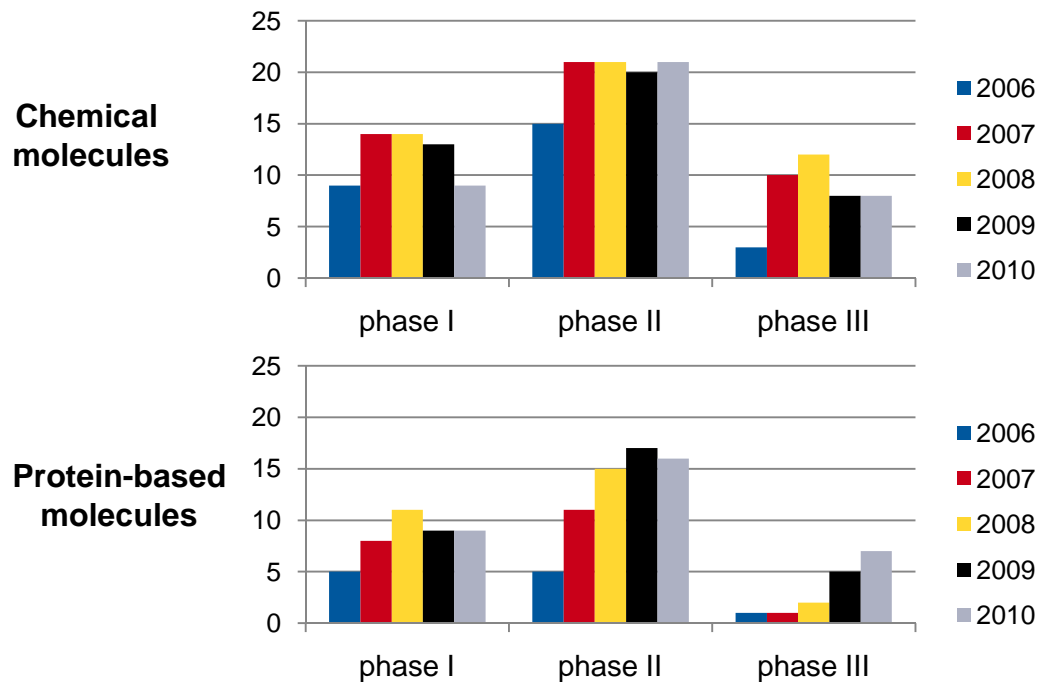


- One project within the therapeutic area CNS and one within infection exited phase III with positive results.
- There was one project within the area cardiovascular, one within immunology and one within transplantation that entered phase III during 2009.
- The two projects within “other” are new from previous years.
- The majority of projects reported to be in phase III previous years remain there.

Source: VINNOVA/SwedenBIO/ISA/analysis -07 and -08,
Note: AstraZeneca products are not included in this graph

Distribution of small and large molecules

Prominent increase in biologics, but chemical molecules still in majority with 6 more projects in phases I-III



Source: VINNOVA/SwedenBIO/ISA analysis -08, -07, -08, 09 and -10
Note: AstraZeneca is not included in this graph

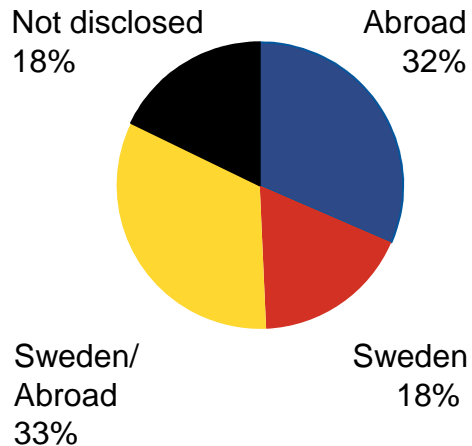
- Out of the 73 projects in phases I–III 2010, 38 are chemical molecules, 32 are protein-based molecules and 5 were not disclosed in the survey.
- Chemically-produced candidates continue to constitute the majority of products in phases I–III.
- The number of projects with protein-based molecules has increased with one project from 2009.

Location of Clinical Trials

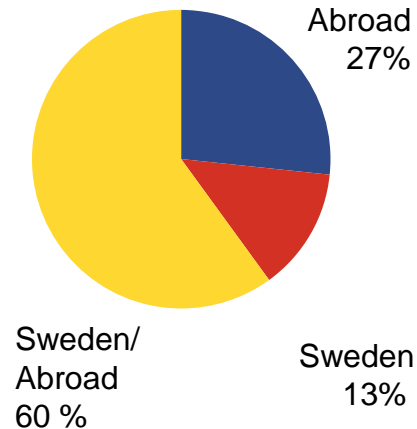
Swedish patients will be included in 11 of 15 phase III projects

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 15 projects in phase III, 9 are tested in clinics both in Sweden and abroad, 4 abroad and 2 in Sweden.
- Of the projects in phases I–III, a minority are tested in Sweden alone.

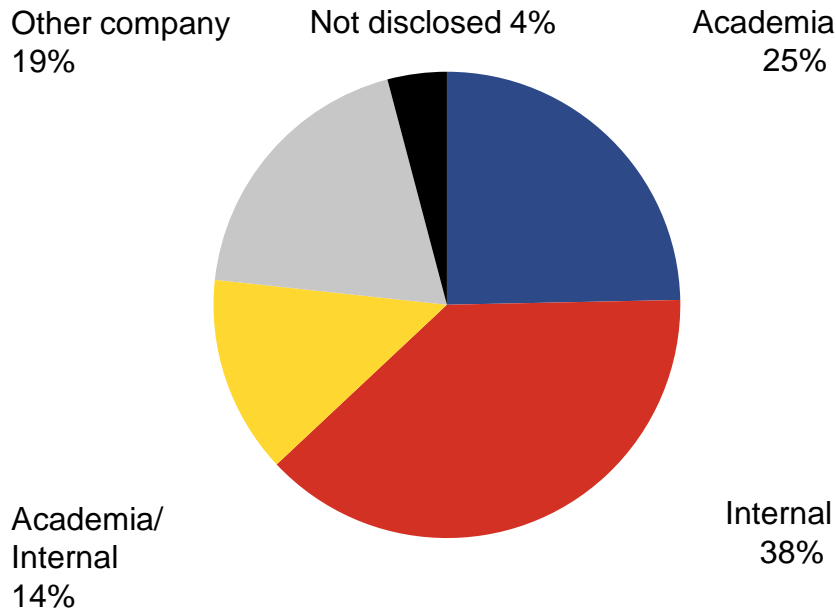
Source: VINNOVA/SwedenBIO/ISA analysis -10
Note: Graph excludes AstraZeneca

Origin of project

Academia is an important contributor to the Swedish drug development pipeline

Origin of project

Phases I–III



Source: VINNOVA/SwedenBIO/ISA analysis -10
Note: Graph excludes AstraZeneca

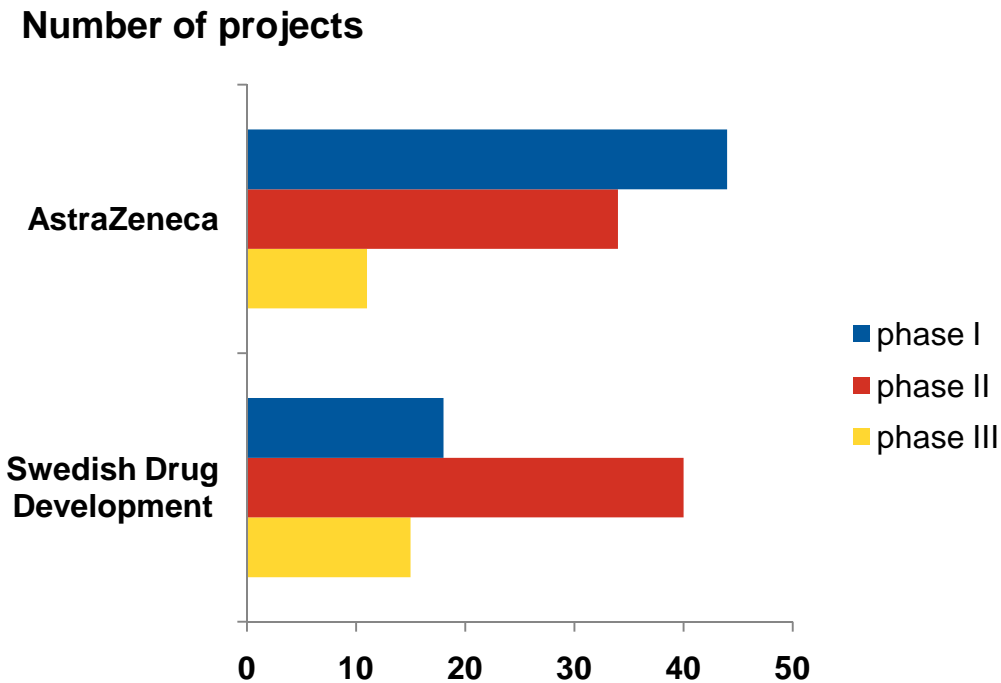
- Most projects in phases I–III originated from research within the company.
- The number of projects originating from cooperation with academia is equal to the number of projects from internal research (39 % vs 38 %)
- One in five projects are procured from other companies and are mainly in phases II and III.

Conclusion

- The Swedish Drug Discovery pipeline is stable and roughly unaltered as compared to 2009.
- There has been a progression through the phases (I-III) and three products were approved by the MPA during 2009.
- There has been a steady increase in the number of projects in phase II. 2006 there were 24 projects reported to be in phase II and 2010 there are 40 projects. This indicates that there most likely are many companies looking for or negotiating with partners to take their projects through phase III. The increase over the years might be a sign of a more harsh financial climate for the big pharma companies.
- Chemical molecules are still in majority with 38 projects compared to 32 protein-based projects, but there is an increase in the number of projects with protein-based molecules in phase III.
- A majority of projects will include patients from both Sweden and abroad in their clinical studies. A minority will be tested in Sweden alone.
- Academia is still a very important contributor to the innovative research and many of the companies in the analysis are founded around ideas and projects originating in academia.

AstraZeneca versus the Drug Development sector

Globally AstraZeneca has 16 more projects in clinical trials as all of the Swedish Drug Development companies together

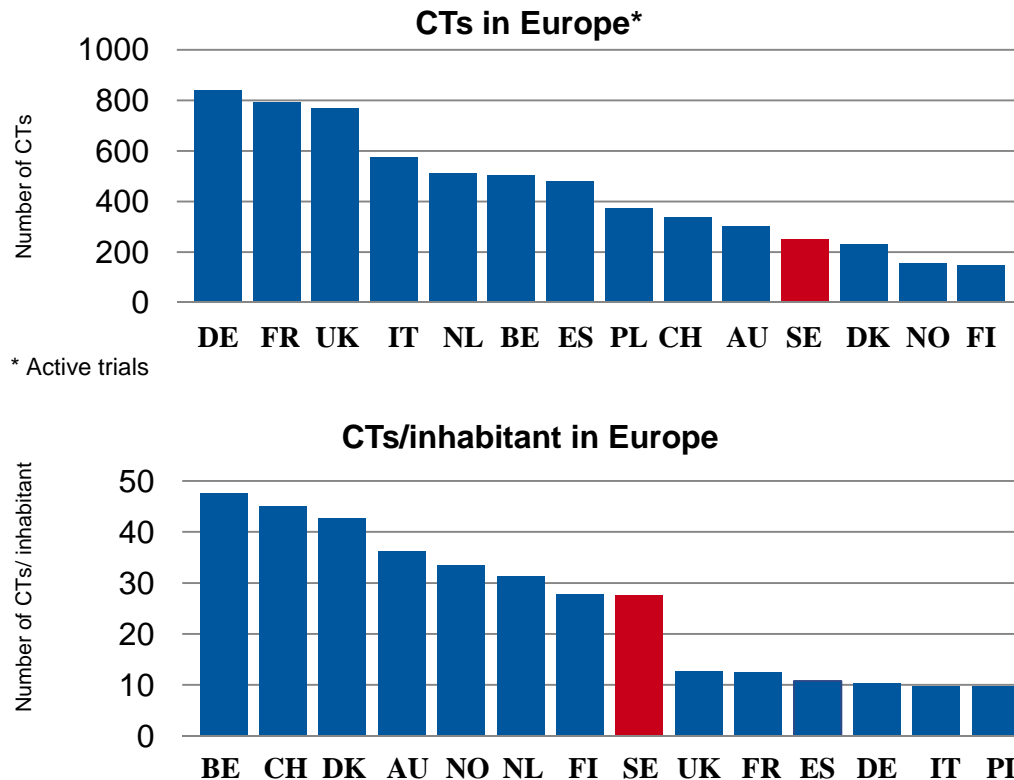


- Globally AstraZeneca has currently 89 projects that are in phases I–III.
- Swedish Drug Development companies together have 73 projects.
- AstraZeneca has an additional 14 products (16 % of the pipeline) in clinical trials that are line extensions.

Source: VINNOVA/SwedenBIO/ISA/analysis -10 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



- In February 2010, around 250 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 infra structure (hospitals, researchers, Medical Product Agency, biobanks et c).

Source: <http://clinicaltrials.gov>; feb 2010

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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