



Dec. 7st, 2016: GTAI Webinar Medical Biotechnology in Germany

Dr. Sabine Sydow, Head of vfa bio

vfa: The Association of Research-Based Pharmaceutical Companies in Germany

- **44 leading research-based pharmaceutical companies** are organized in the vfa
- Together with their more than 100 subsidiaries and affiliated companies, they employ **nearly 80,000 people in Germany.**
- The vfa members represent **more than two-thirds of the entire German pharmaceutical market.**
- They **guarantee therapeutic progress** in pharmaceuticals and ensure high-quality pharmaceutical therapy.
- In Germany more than **18,000 of their employees** work in the field of research and development of pharmaceuticals. Here, the research-based pharmaceutical companies **invest EUR 5.2 billion per year in pharmaceutical research.**
- **vfa bio** is the interest group biotechnology within the vfa



Biotech within Research-Based
Pharmaceutical Companies

11 Biotech Reports since the foundation of vfa bio in 2006

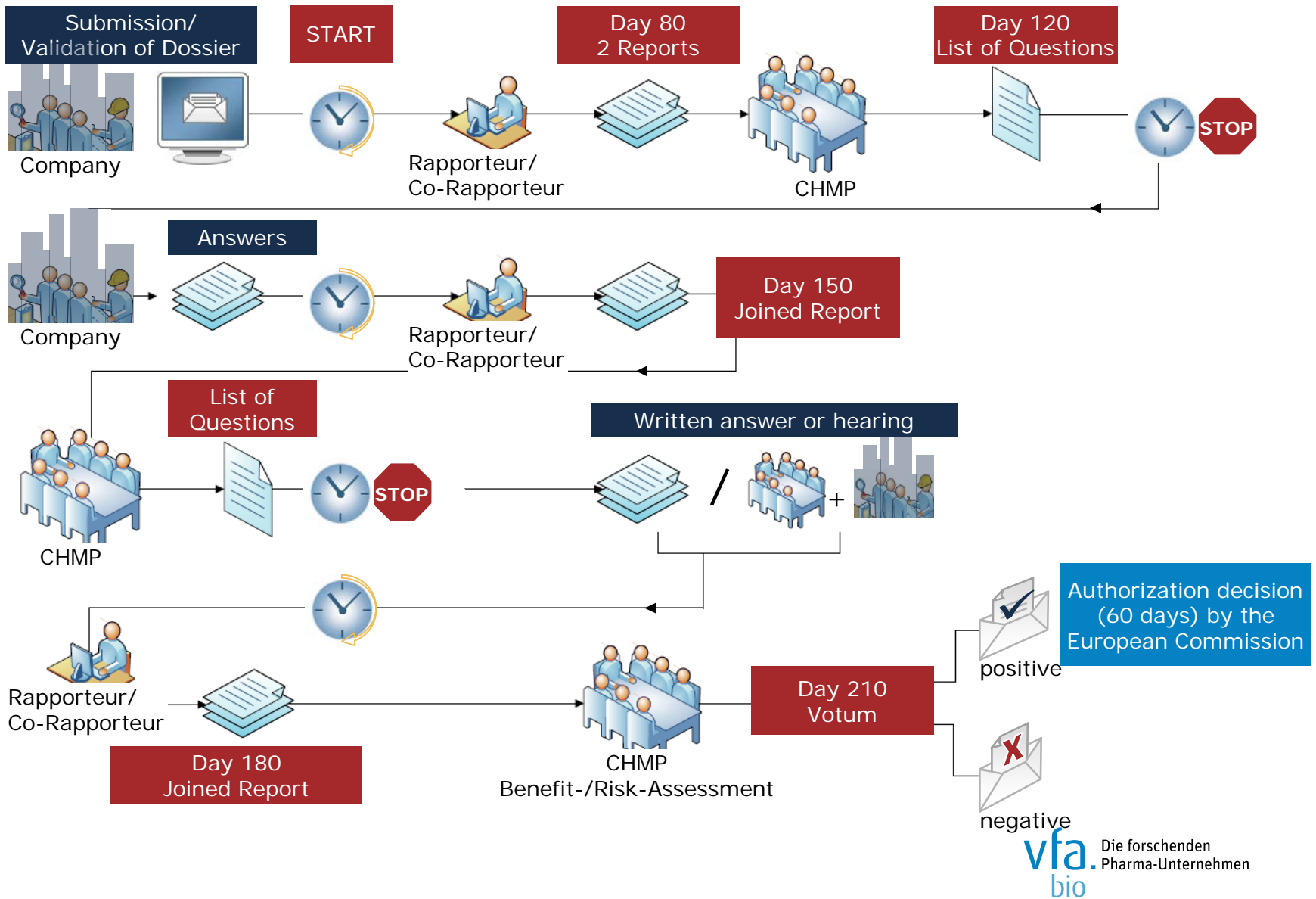


The EU's centralized authorization procedure

- **Compulsory for** e.g. biopharmaceuticals, orphan drugs and advanced therapy medicinal products
- Manufacturer can obtain **scientific advice** from EMA experts
- Documents are submitted to the EMA
(since 2006 risk management plans are mandatory
⇒ obligation to conduct non-interventional/
observational studies after registration)
- **Assessment by two rapporteurs** (national regulatory institutions);
if applicable recommendation („**positive opinion**“) of the EMA by
the Committee for Medicinal Products for Human Use (CHMP)
- **Final approval decision** by the European Commission (publication
in the Official Journal of the EU)
- **More than 500 registrations** in the EU since 1995

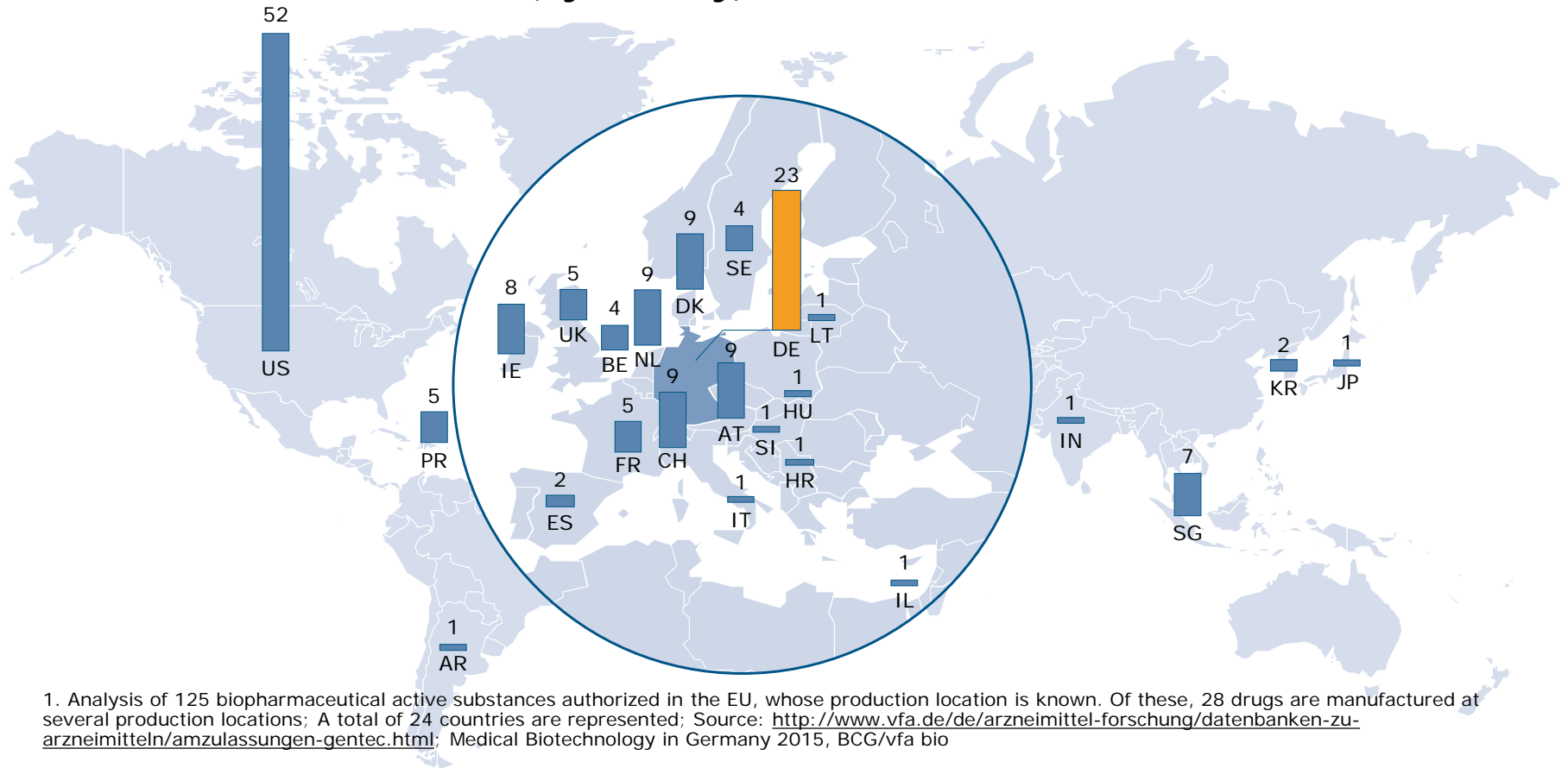


Centralized authorization procedure (EU)



Germany is at the top in Europe in the production of biopharmaceuticals authorized in the EU

Number of produced biopharmaceutical active substances per country which have been authorized in the EU (by country)¹

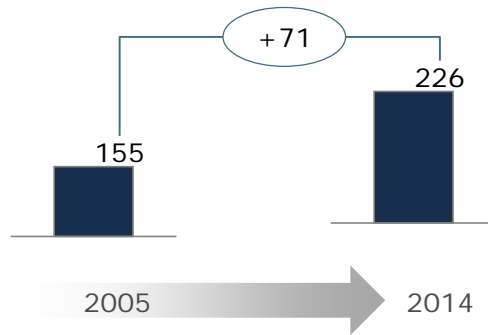


1. Analysis of 125 biopharmaceutical active substances authorized in the EU, whose production location is known. Of these, 28 drugs are manufactured at several production locations; A total of 24 countries are represented; Source: <http://www.vfa.de/de/anzneimittel-forschung/datenbanken-zu-anzneimitteln/amzulassungen-gentec.html>; Medical Biotechnology in Germany 2015, BCG/vfa bio

10-year comparison: Growing importance of biopharmaceuticals in Germany

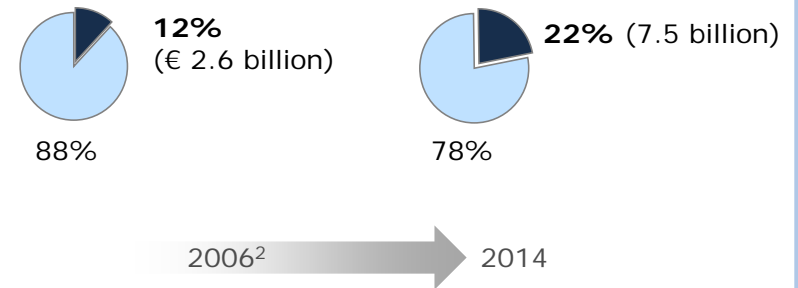
Marketing authorizations

Well over 200 biopharmaceuticals on the market¹



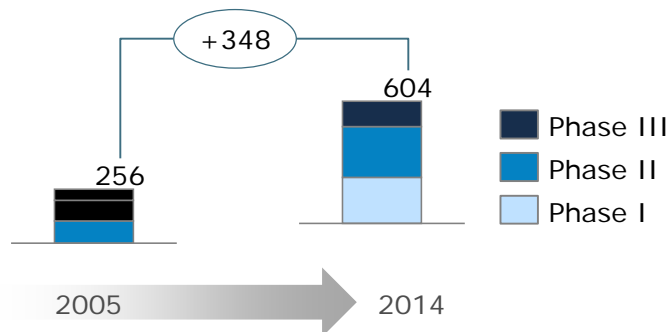
Market share of biopharmaceuticals

Market share of biopharmaceuticals on the total pharmaceuticals market has almost doubled



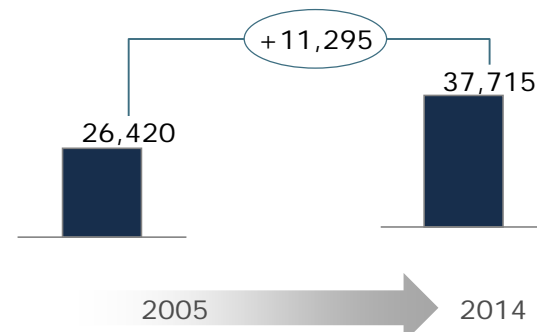
Pipeline

Number of pipeline products has more than doubled



Employment

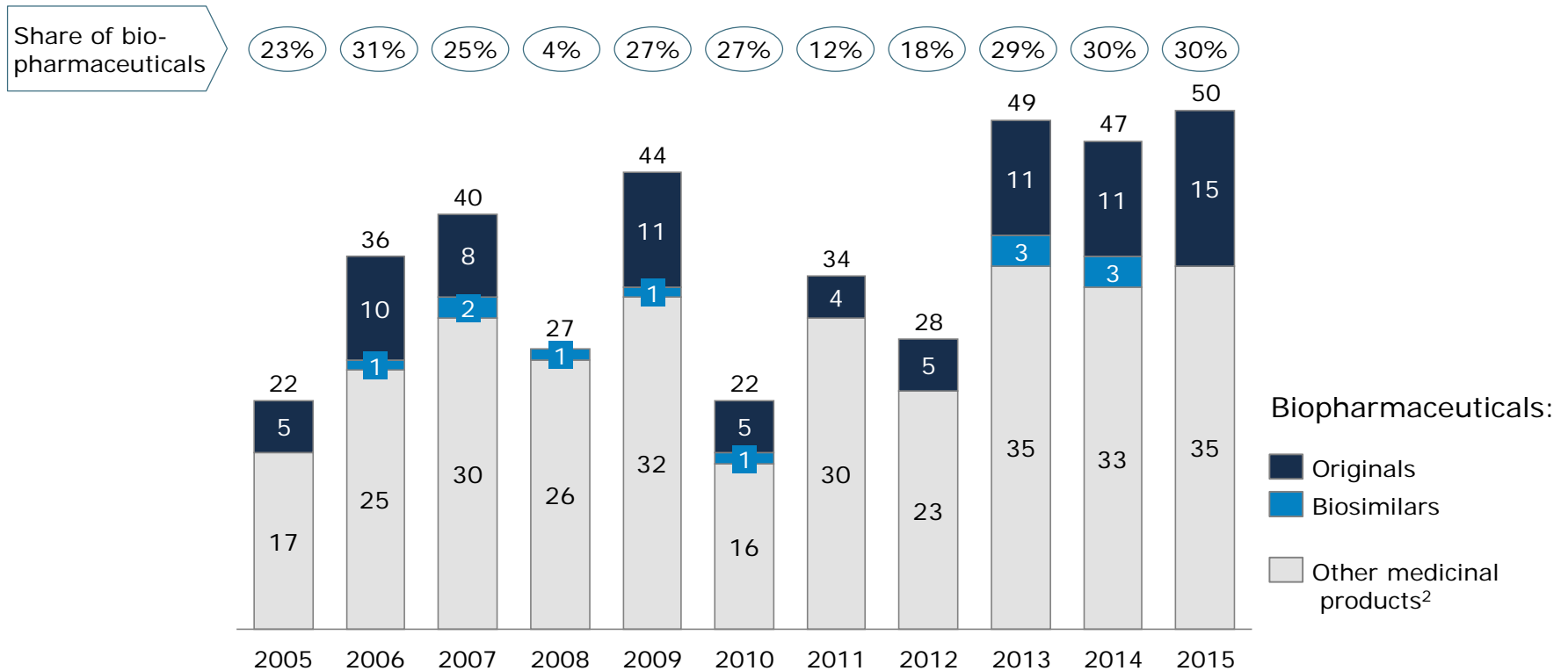
Continuously increasing employment figures



1. Includes biotechnologically and genetically manufactured vaccines 2. First itemisation in the Biotech Report 2007 for the calendar year 2006
Source: Medical Biotechnology in Germany 2015, BCG/vfa bio

15 newly authorized original biopharmaceuticals: More than ever before

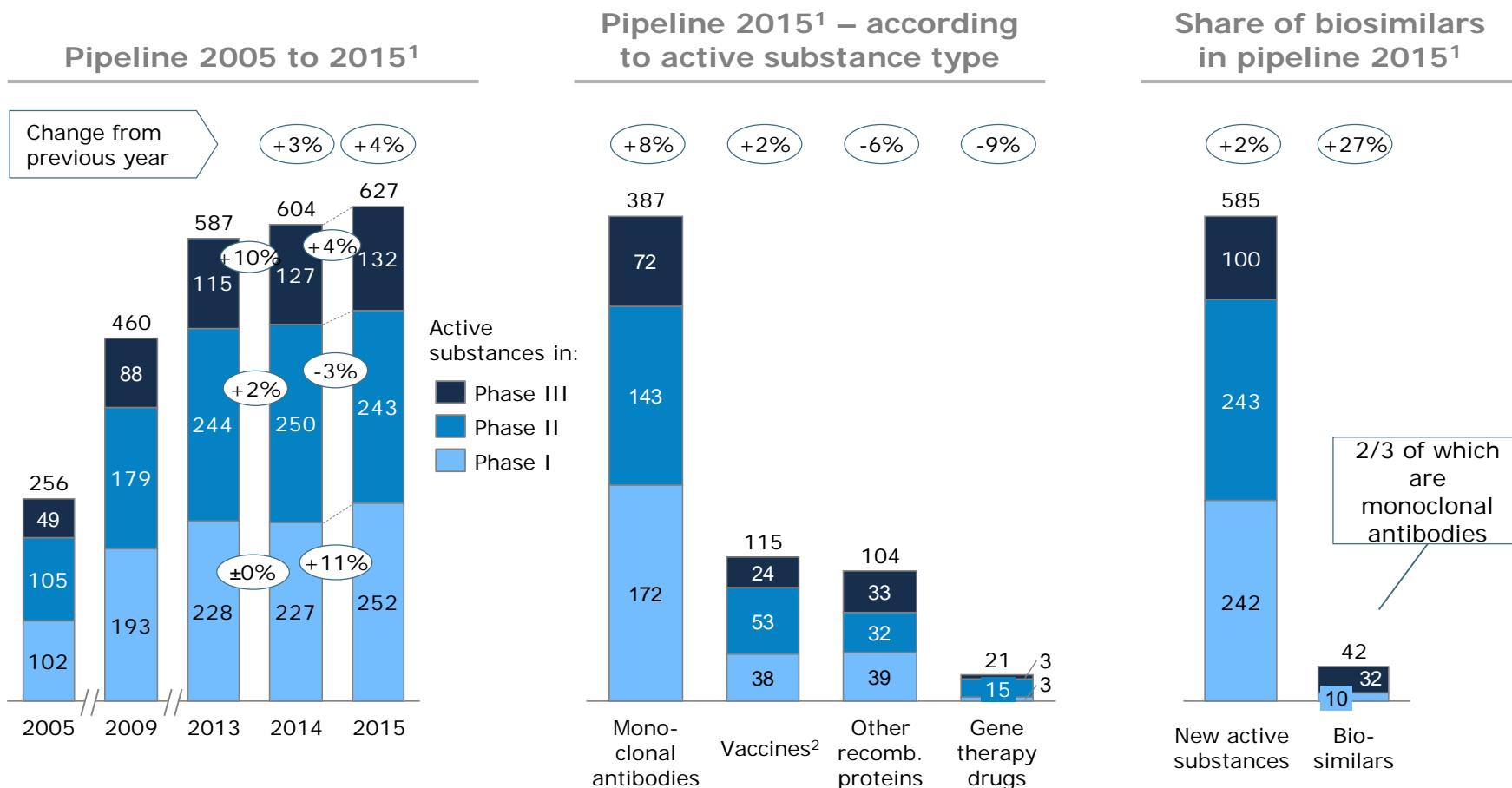
Number of new marketing authorizations¹



1. New authorizations in Germany/EU; new active substances or new combinations of known active substances including biosimilars 2. With chemical and other active substances; Source: EMA; European Commission; vfa; BCG analysis; Source: Medical Biotechnology in Germany 2016, BCG/vfa bio

Biopharmaceutical pipeline

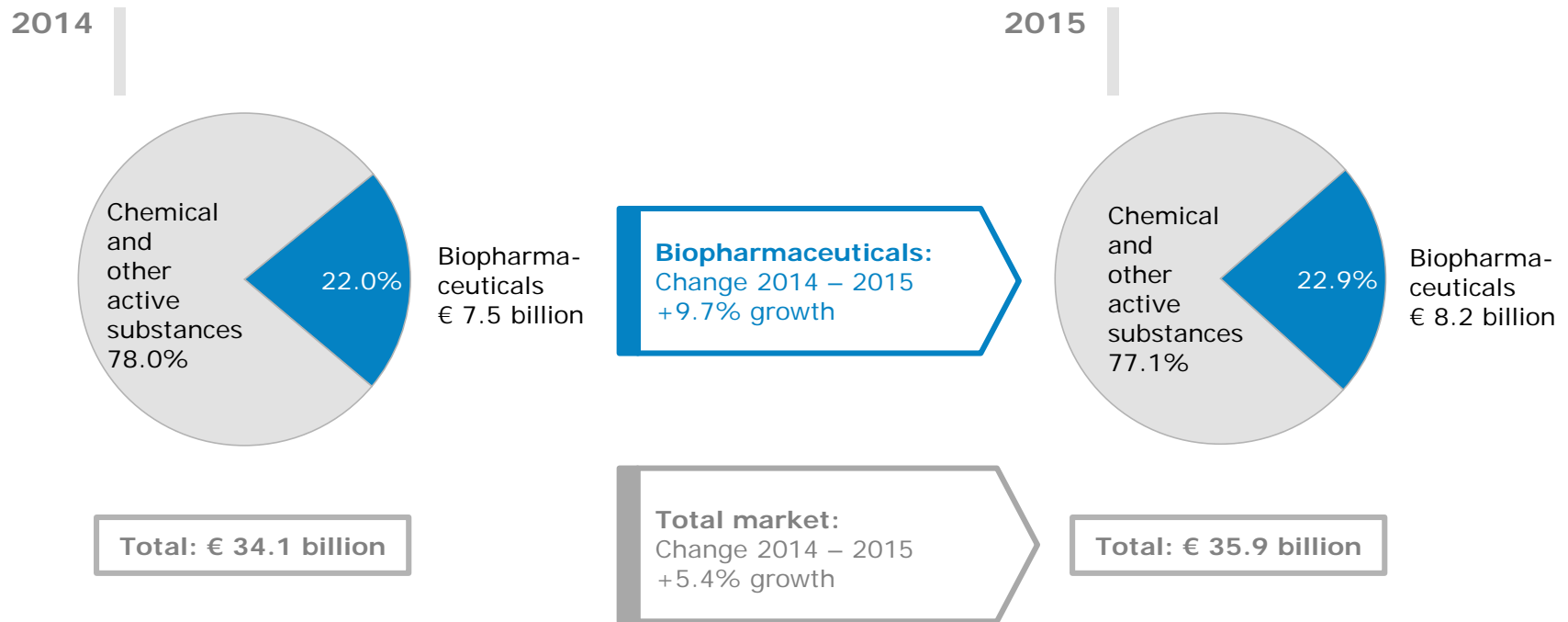
sees double-digit growth in Phase I of clinical development



1. Number of new active substances in the most advanced phase 2. Biotechnologically and genetically manufactured
 Comment: Phase I/IIa included in Phase I; Active substances in approval procedure included in Phase III; Active substances in global studies conducted by companies operating in Germany; Source: EvaluatePharma; Citeline's Pharmaprojects Pipeline Service, Jan 2016; vfa; Company information; BCG analysis; Medical Biotechnology in Germany 2016, BCG/vfa bio

The importance of biopharmaceuticals continues to increase

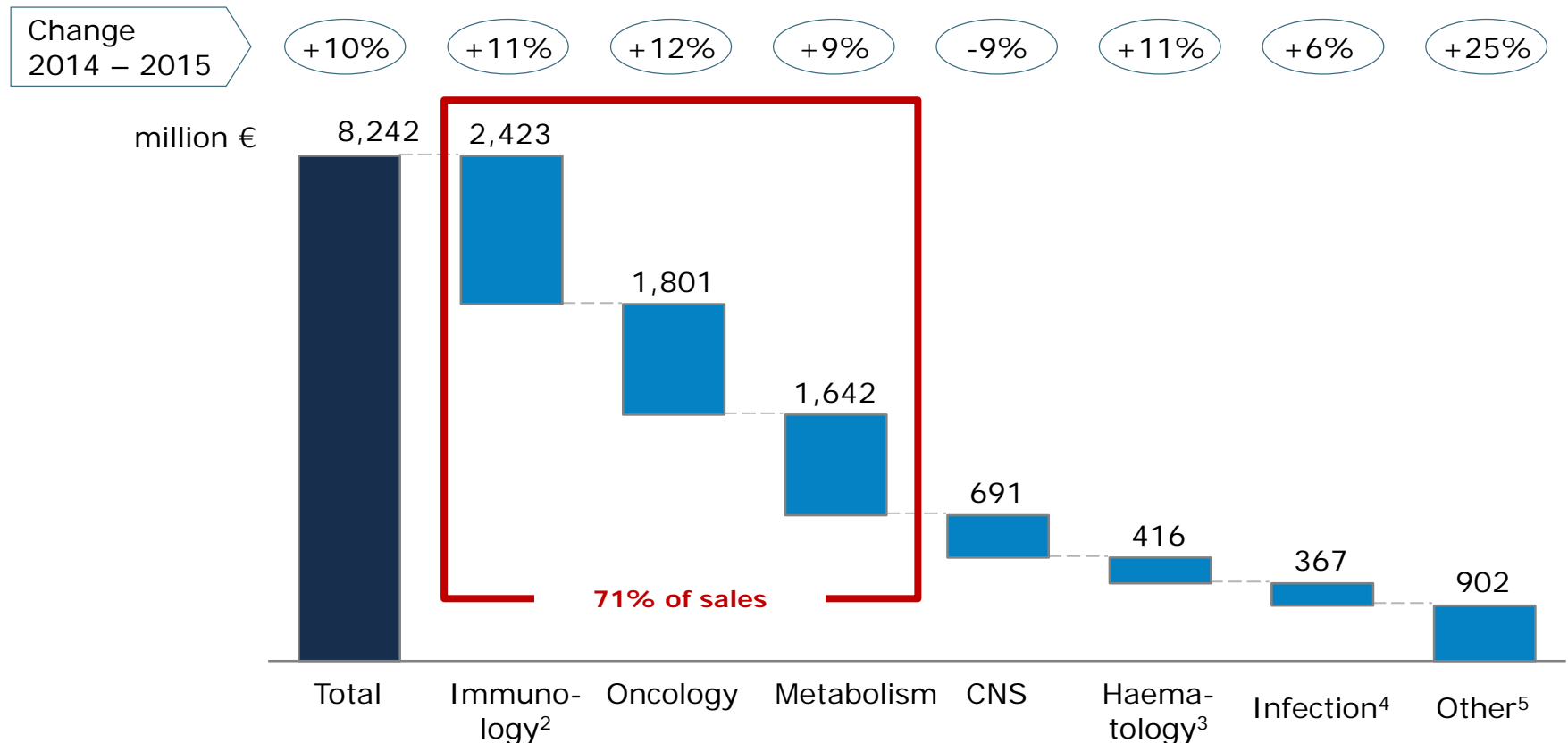
Sales and share of biopharmaceuticals in the total pharmaceuticals market^{1, 2}
(net, Germany, in billion euros [€])



1. Total net sales (pharmacy and hospital market in the statutory and private health insurance sectors) according to the ApU (selling price of pharmaceutical companies) minus the statutory manufacturers' rebates 2. IMS Health
Comment: Biopharmaceuticals = medicinal products whose active substances are manufactured using genetically altered organisms; Source: IMS Health; BCG analysis; Medical Biotechnology in Germany 2016, BCG/vfa bio

More than two thirds of sales are in immunology, oncology and metabolism

Sales¹ of biopharmaceuticals in Germany 2015



1. Total net sales (pharmacy and hospital market in the statutory and private health insurance sectors) according to the ApU (selling price of pharmaceutical companies) minus the statutory manufacturers' rebates 2. Includes TNF- α inhibitors; excludes multiple sclerosis (s. CNS) 3. Excludes haematological oncology 4. Includes vaccines and antiviral active substances 5. Includes osteoporosis, eye and respiratory diseases; Source: IMS Health; BCG/vfa bio
 Medical Biotechnology in Germany 2016, BCG/vfa bio

Medical biotechnology in Germany 2025: Seven theses at a glance

- 1 Companies are investing continuously in the biopharmaceutical pipeline:** High number of development candidates in pipeline, share of new approvals around 30-40%
- 2 Benefits for more and more patients:** New approvals and indication extensions will enable more patients to be treated with biopharmaceuticals in the future
- 3 Unmet medical need:** Biopharmaceuticals will become established in further areas of application
- 4 Renaissance of vaccines:** The importance of vaccines will increase, particularly with the introduction of therapeutic vaccines
- 5 Personalized medicine a growing trend:** The share of personalized/stratified biopharmaceuticals will increase significantly
- 6 Biopharmaceutical advances thanks to new technologies:** New analysis concepts and therapeutic applications will continue to improve treatment options for patients
- 7 On the way from manufacturer to healthcare partner:** Not only biopharmaceuticals themselves but also the involvement in the provision of integrated healthcare will be crucial



Thank you very much for your attention!