

Appendix 1: Data sources used in the study ‘Development in the number of clinical trial applications in Western Europe from 2007 to 2015: retrospective study of data from national competent authorities’

Data sources
<p>Austria National competent authority (NCA): Österreichische Agentur für Gesundheit und Ernährungssicherheit (AGES)</p> <p>Data from:</p> <ol style="list-style-type: none">1) ‘Clinical Trials: Statistics 2015’: http://www.basg.gv.at/fileadmin/user_upload/BASG_CLTR_CT_Statistics_2016_EN.pdf
<p>Belgium NCA: The Federal Agency for Medicines and Health Products (FAMHP)</p> <p>Data from:</p> <ol style="list-style-type: none">1) Personal communication per email with FAMHP2) Report: ‘Clinical Research Footprint and Strategic Plan to Promote Clinical Trials in Belgium’, June 2012, published by PricewaterhouseCoopers (PWC)
<p>Germany NCAs: Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) and Paul-Ehrlich-Institut (PEI)</p> <p>Data from:</p> <ol style="list-style-type: none">1) Personal communication per email with BfArM and PEI2) ‘Statistik: Anträge auf Genehmigung einer Klinischen Prüfung’: http://www.bfarm.de/DE/Arzneimittel/zul/klinPr/klin_prf_genehm/Statistik.html3) ‘Processing statistics for applications for clinical trials at the Paul-Ehrlich-Institut’: http://www.pei.de/EN/information/license-applicants/clinical-trial-authorisation/statistics/statistics-clinical-trials-node.html

Denmark

NCA: Lægemiddelstyrelsen

Data from:

- 1) 'Årsrapport 2015 Kliniske forsøg med lægemidler':
<https://laegemiddelstyrelsen.dk/da/udgivelser/2016/kliniske-forsog-med-laegemidler-aarsrapport-2015>

Spain

NCA: Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

Data from:

- 1) 'Memoria de actividades de la AEMPS 2007 to 2015':
<https://www.aemps.gob.es/laAEMPS/memoria/home.htm>

France

NCA: Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM)

Data from:

- 1) 'Rapport d'activité 2015 de l'ANSM':
<http://ansm.sante.fr/S-informer/Points-d-information-Points-d-information/L-ANSM-publie-son-rapport-d-activite-2015>
- 2) 'ANSM - Annual report 2014 and 2013':
<http://ansm.sante.fr/Mediatheque/Publications/Information-in-English>
- 3) Report: 'Rapport Annuel 2007 Afssaps', June 2008, Published by Agence française de sécurité sanitaire des produits de santé (Afssaps)

Italy

NCA: Agenzia Italiana del Farmaco (AIFA)

Data from:

- 1) 'Report clinical trials of drugs in Italy, Annual reports 2009 to 2015':
<http://www.agenziafarmaco.gov.it/en/content/bulletin-clinical-trials-drugs-italy>

The Netherlands

NCA: Centrale Commissie Mensgebonden Onderzoek (CCMO)

Data from:

- 1) Personal communication per email with CCMO
- 2) 'CCMO-jaarverslag 2007 to 2015':
<http://www.ccmo.nl/en/publications-of-the-ccmo>

Sweden

NCA: Läkemedelsverket

Data from:

- 1) Personal communication per email with Läkemedelsverket

The United Kingdom

NCA: Medicines & Healthcare products Regulatory Agency (MHRA)

Data from:

- 1) 'Clinical trials for medicines: authorisation assessment performance':
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/552367/07_Aug_2016.pdf

Poland

NCA: Urząd Rejestracji Produktów Leczniczych (URPL)

Data from:

- 1) Personal communication per email with URPL

Hungary

NCA: Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet (OGYÉI)

Data from:

- 1) Personal communication per email with OGYÉI

Romania

NCA: Agentia Nationala a Medicamentului si a Dispozitivelor Medicale (ANM)

- 1) '2012 Annual report The national agency for medicines and medical devices':
<http://www.anm.ro/anmdm/en/ACTIVITY%20REPORTS/Activity%20report%202012.pdf>
- 2) 'The national medicines agency 2007 annual report':
<http://www.anm.ro/anmdm/en/ACTIVITY%20REPORTS/2007%20Activity%20report.pdf>

The Czech Republic

NCA: Státní ústav pro kontrolu léčiv (SÚKL)

Data from:

- 1) 'Annual reports 2007 to 2015':
<http://www.sukl.eu/sukl/annual-reports>