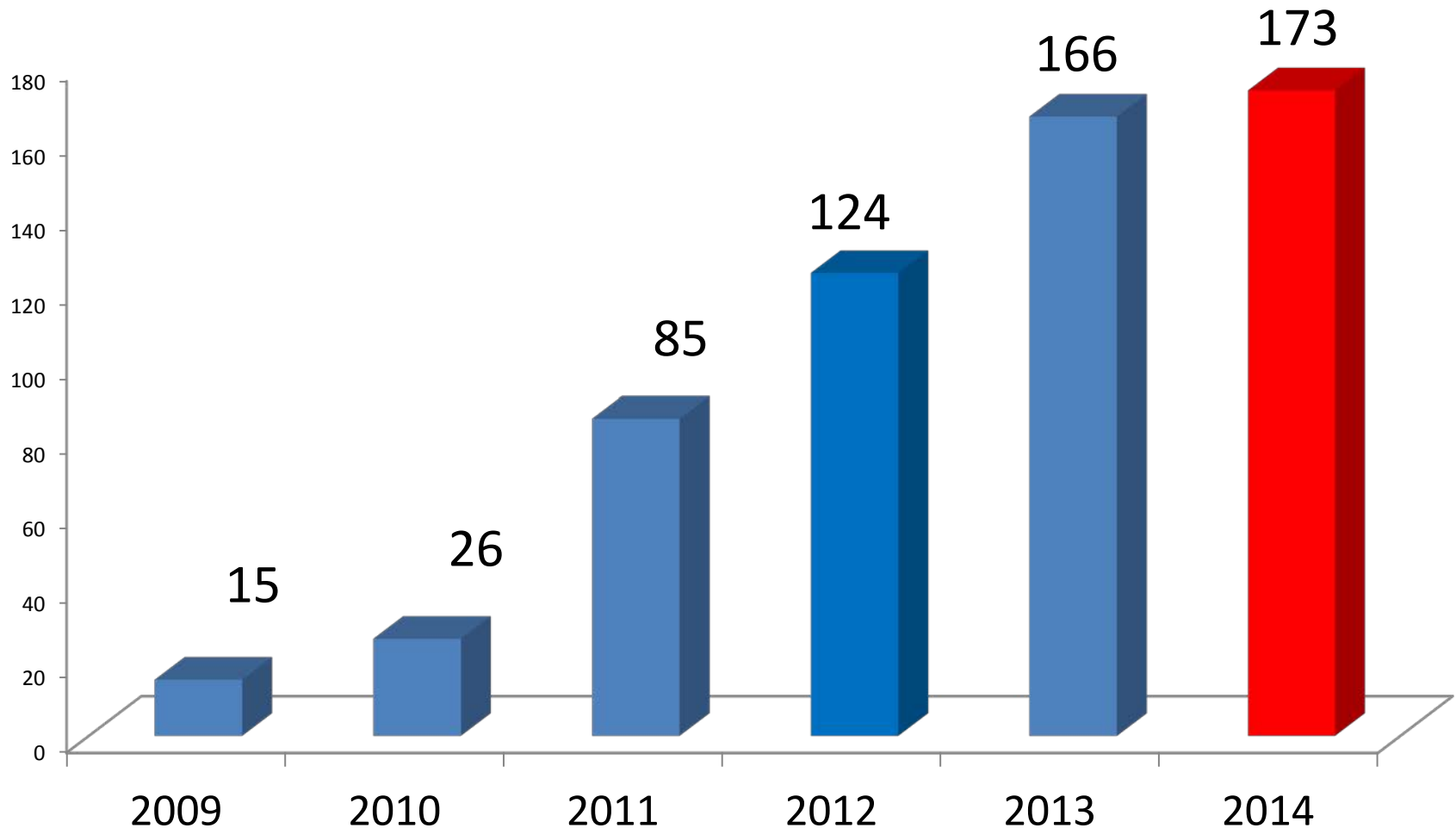


Results of the Voluntary Harmonisation Procedure 2009 – 2014

HMA's Clinical Trials Facilitation
Group

Status 20.1.2015

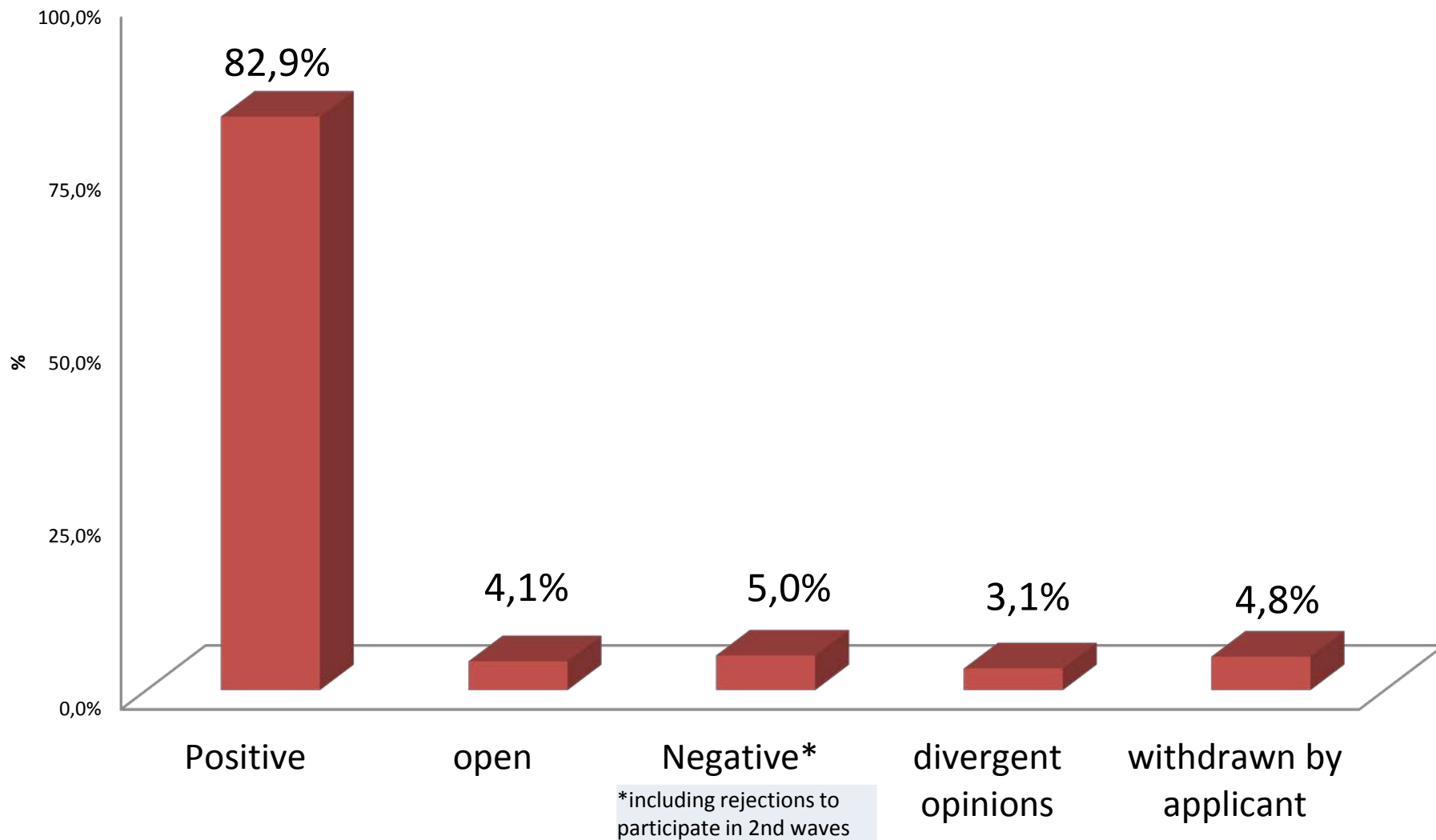
No. of VHPs per submission year



The graph depicts evaluable Voluntary Harmonisation Procedures excluding 11 procedures from the pandemic influenza situation in 2009

As in 2013 almost 20% of all multinational clinical trials in Europe underwent a VHP before they were submitted to the National competent authorities in 2014

Percentage of VHP decisions from 3/2009 to 31.12.2014

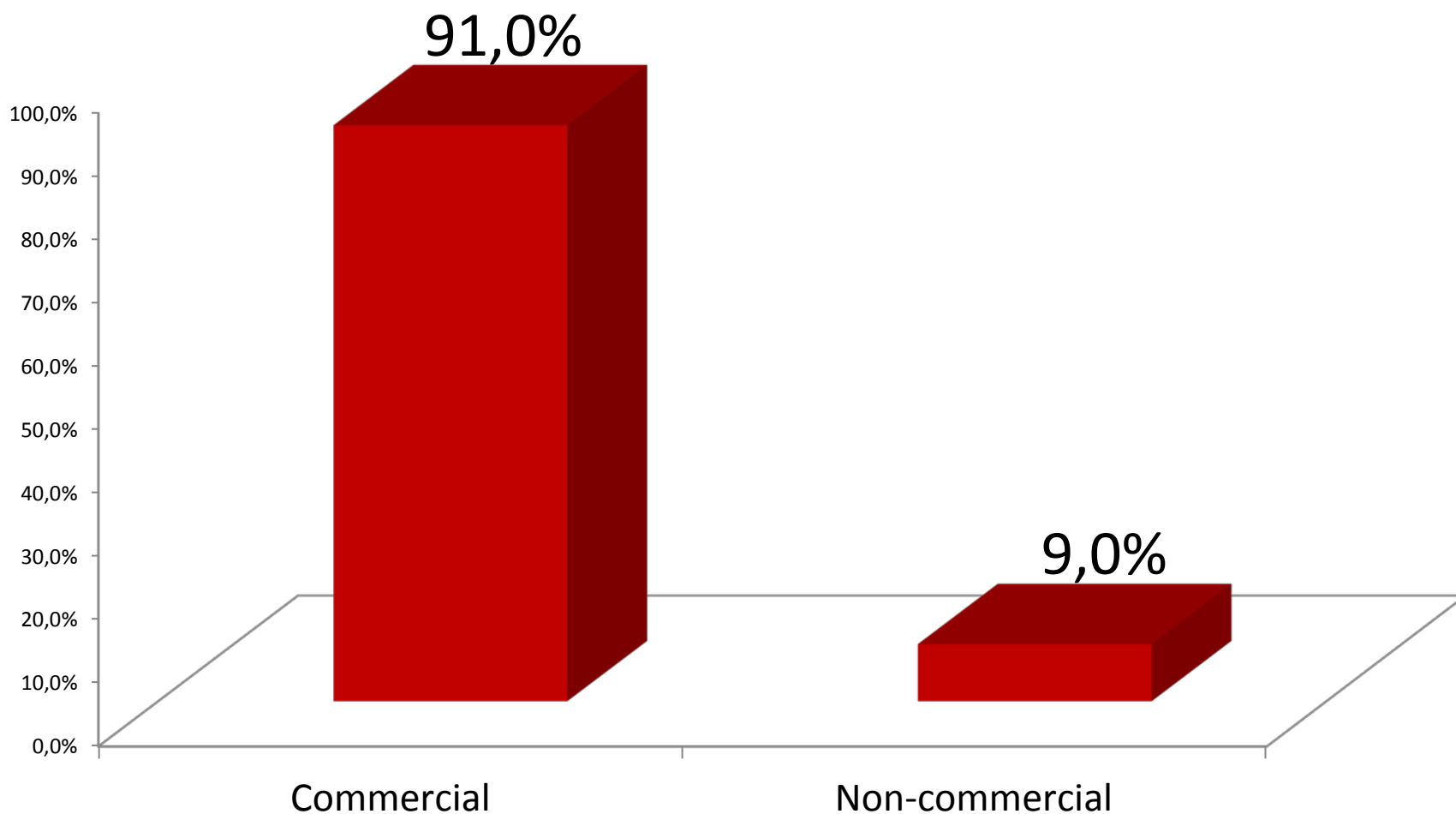


The graph depicts evaluable Voluntary Harmonisation Procedures excluding 11 procedures from the pandemic influenza situation in 2009

Times for a VHP Decision

	Days
mean time from start VHP until the end (without open / withdrawn, Christmas special, ATMPs and accelerated VHPs but including the time for response to GNA for Sponsors)	52,5
Minimum in days	0
Maximum in days	75
STD in days	14,3

Distribution of commercial / non-com. Sponsors in VHP



Distribution of regions/countries of VHP sponsors

Country of Sponsor	Number of Voluntary Harmonisation Procedures
United States of America	216
SWITZERLAND	106
Germany	73
FRANCE	45
UNITED KINGDOM	42
DENMARK	25
SWEDEN	24
BELGIUM	23
SPAIN	11
IRELAND	6
CANADA	5
CZECH REPUBLIC	4
AUSTRIA	3
AUSTRALIA	3
ITALY	3
NETHERLANDS	3
SINGAPORE	3
ISRAEL	2
JAPAN	1
PORTUGAL	1

The total number of different sponsors is 165

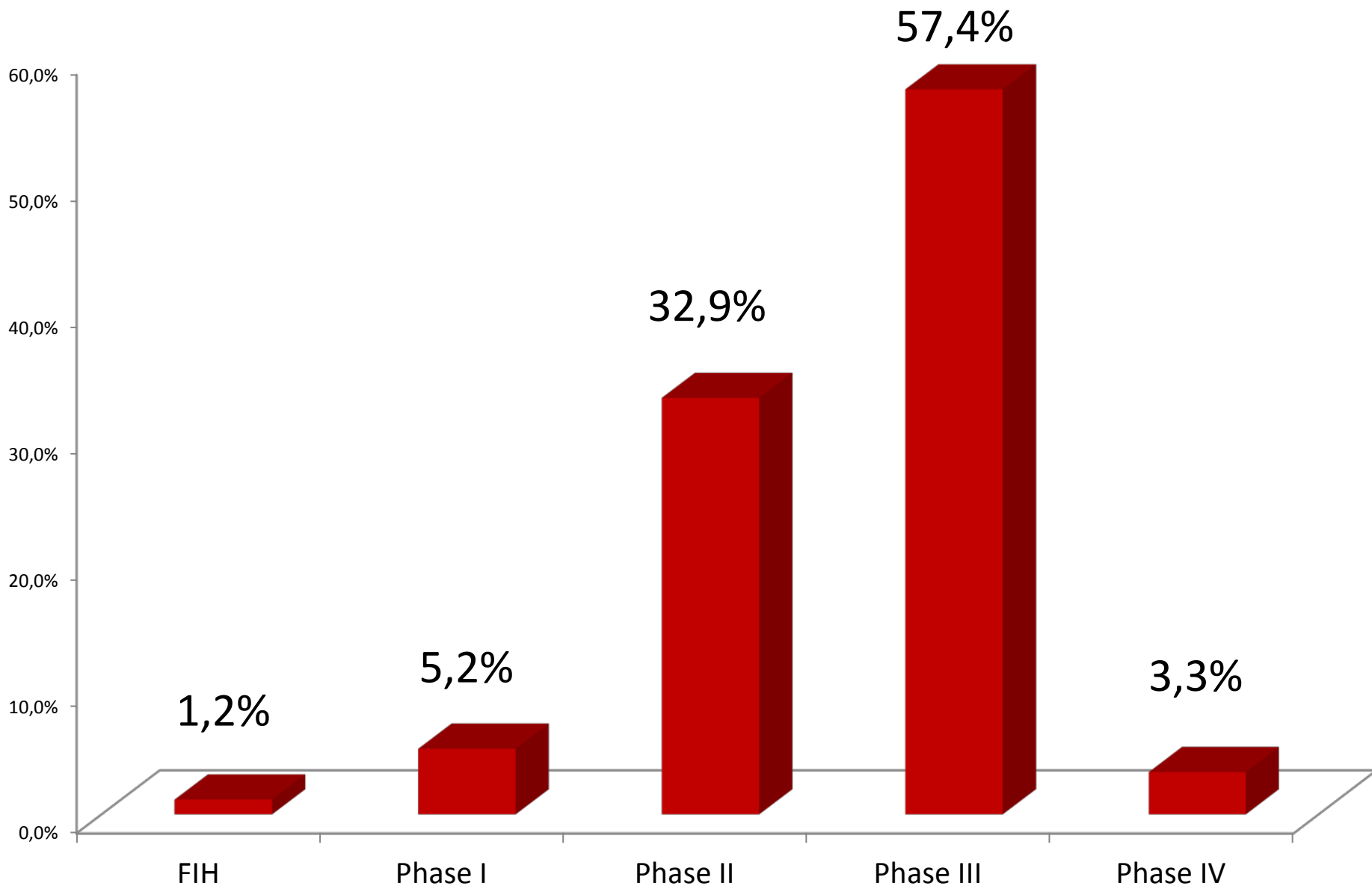
Member States joining the VHP

mean of Member States per Voluntary Harmonisation Procedure	6
min	2
max	16

Distribution of IMPs

Group IMP	Percentage
Chemicals	49,9
Biologicals	50,1

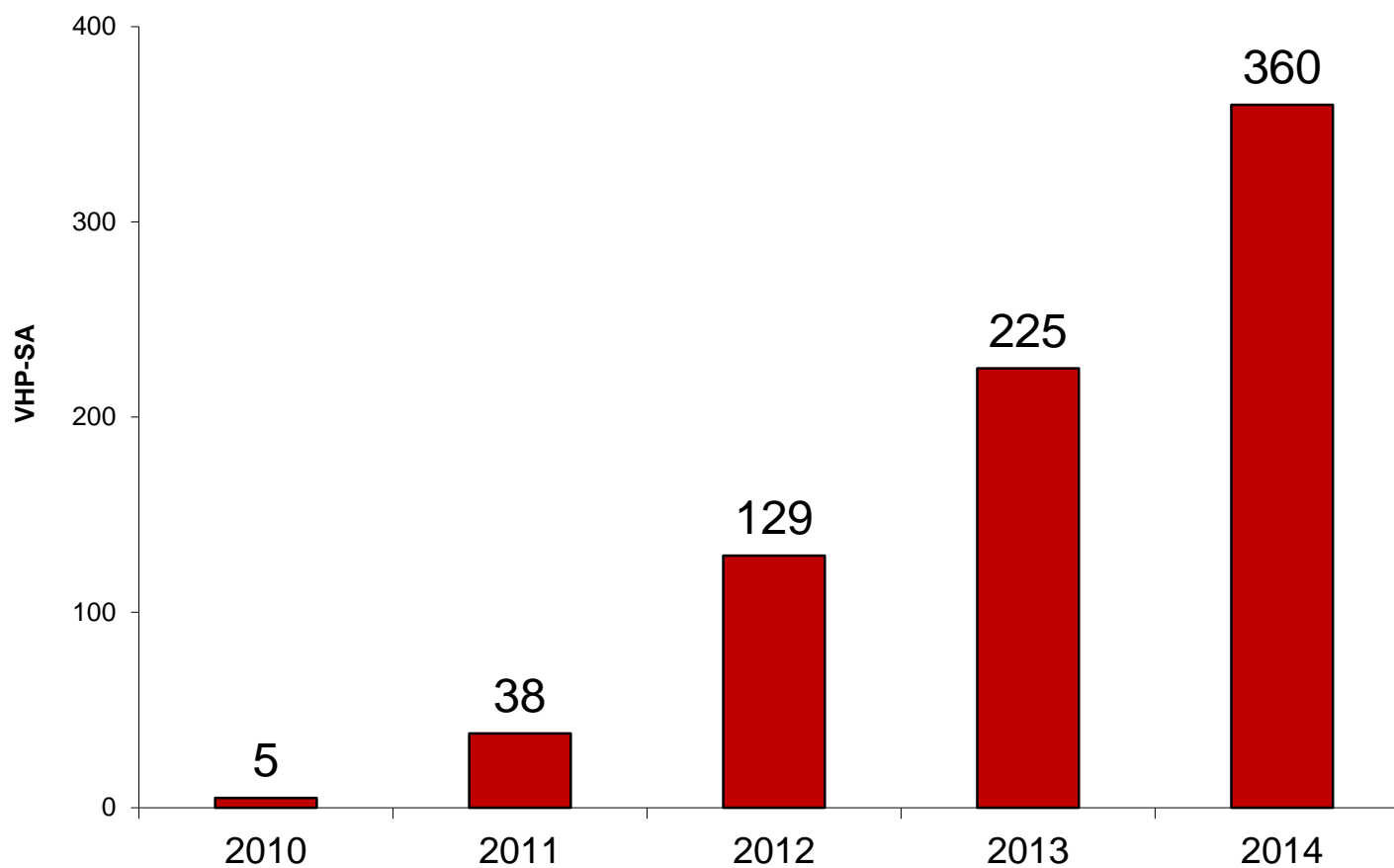
Distribution of VHPs by phase of clinical trial



Status of the IMP

Status marketing authorisation	Percentage
authorised	16,4
non-authorised	83,6

Numbers of VHP-SA 2009- 2014



questions / comments can be sent via
mail to

VHP-CTFG@VHP-CTFG.eu