

# Benefits of a simplified and coherent clinical trials framework in Europe:

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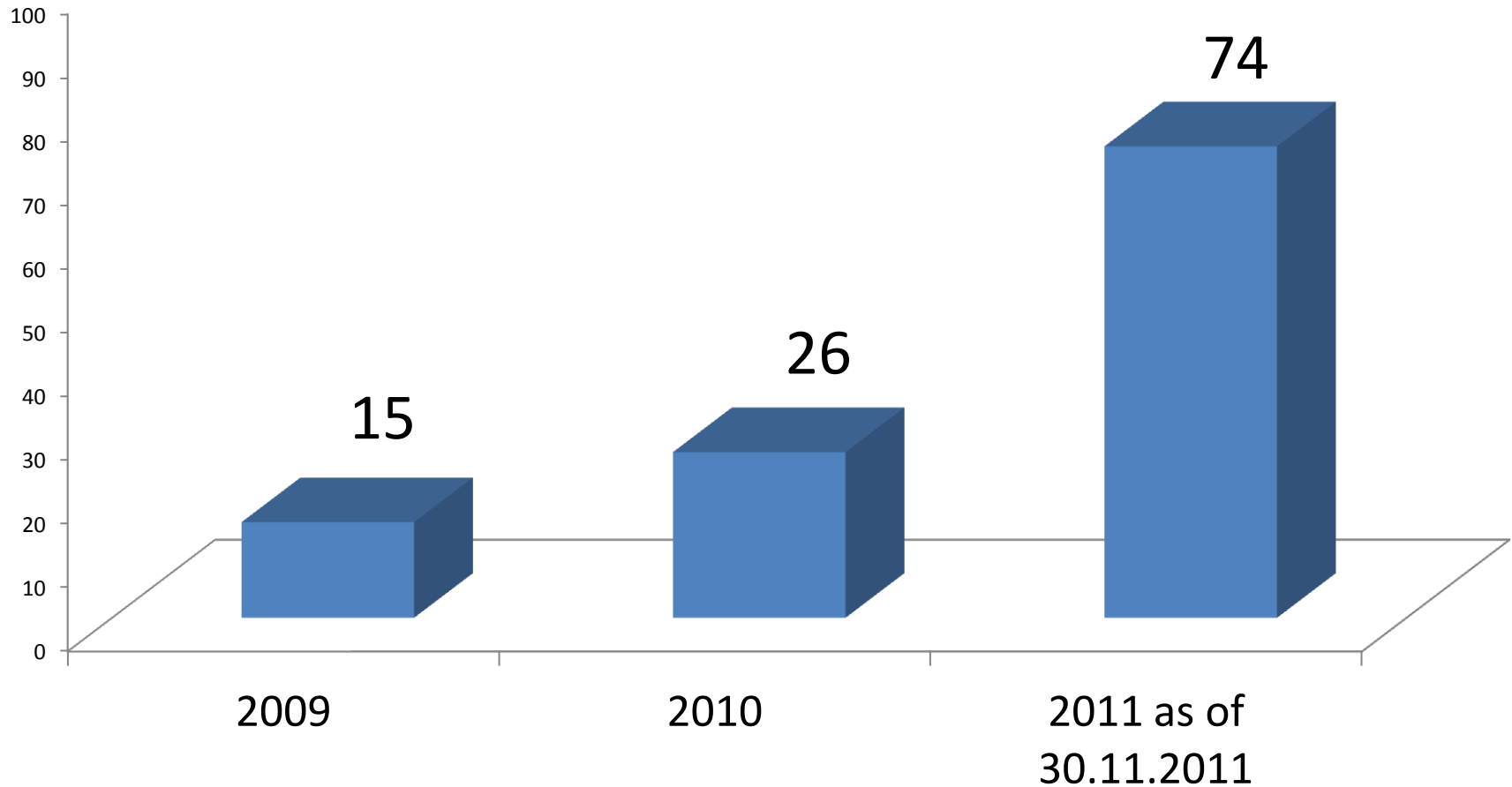


# Key features of the Voluntary Harmonisation Procedure (VHP)

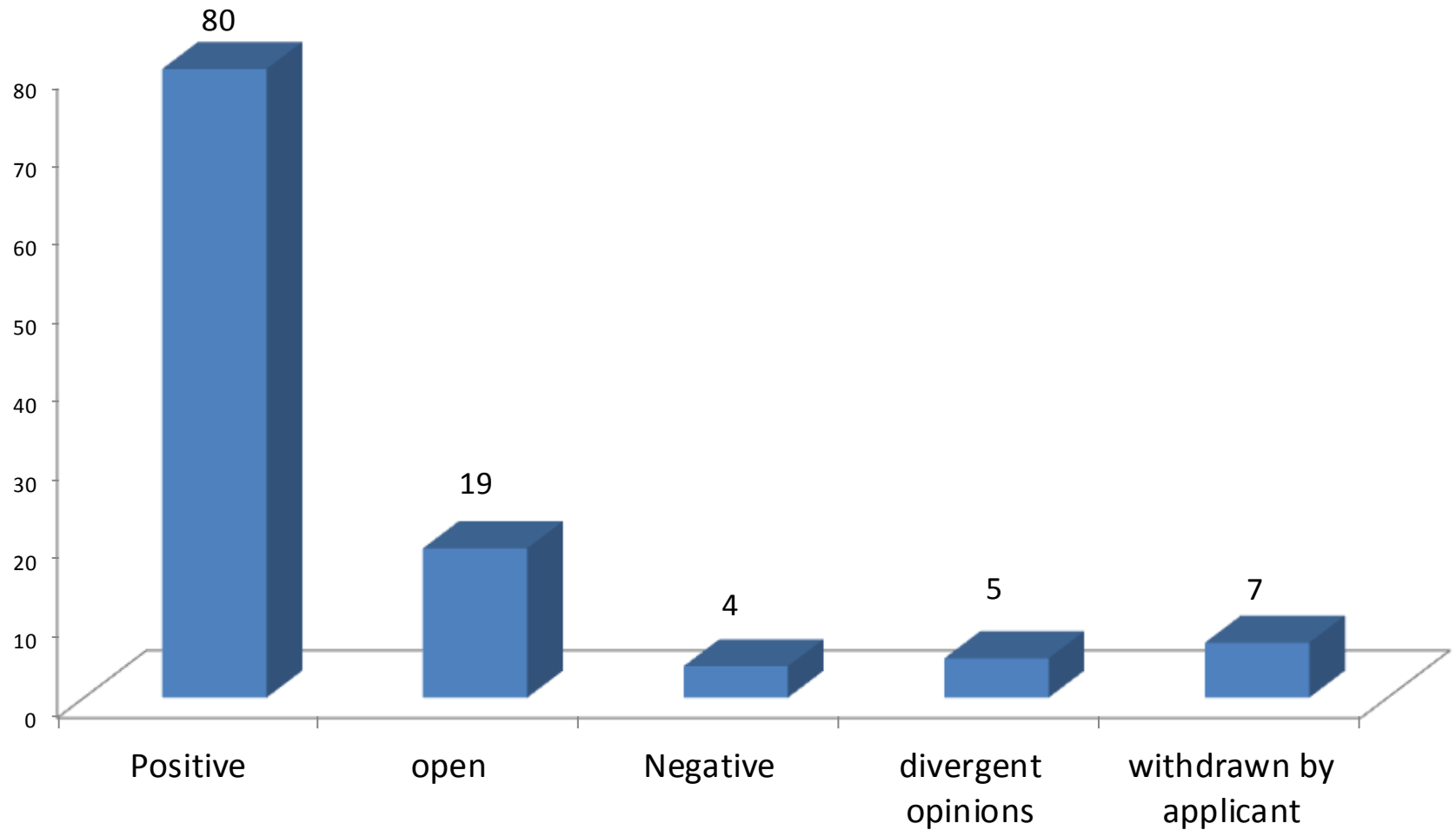
- **Flexibility** and active management, when needed
- Only electronic documents sent to one address (**one stop shop**)
- Only **general documents** required, which are part of any clinical trial application (Protocol, Investigators brochure, Investigational Med. Product Dossier)
- **Reliable timelines** for Sponsor and Member States
- Harmonised scientific discussion resulting in harmonised applications in the Member States
  - **consolidated lists of grounds for non-acceptance**, if needed
  - >95% harmonised decisions between the nominated Member States



# No. of VHPs per submission year



# VHP decisions from 3/2009 to 11/2011



# Summary results of the VHP

(March 2009 - November 2011)

- **Clinical Trial Application**
  - 115 procedures (74 until 30.11.2011)
    - (39 USA; 13 Switzerland; Rest EU)
  - 58 different sponsors
  - ~80% commercial, ~20 % NC
  - 6 MS per VHP in average
  - 50 days average time until decision
  - Reduction  $\simeq$  50% of GNA by LMS/REF-NCA
  
- **SUBSTANTIAL AMENDMENT**
  - 35 SA from 25 VHPs
  - 20.5 days for CTFG assessment



# Summary Position on the coordinated assessment process (CAP)



# CTA process and assessment

**We support simplification of CTA process:**

- Single EU portal endorsed, but
  - Step wise implementation (start with /limit to MN-CTs); really needed for Clinical Trials in one MS only?
  - Challenging (ECs + NCAs)

**We support coordination of CTA Assessment by MS**

- CT authorisation still at National level
- Flexibility maintained
- Legal Basis to the VHP work-sharing approach for MN-CTs is needed;
- Legal basis to CTFG is required.



# The coordinated assessment process (CAP)

- General principles of CAP are supported
- Reporting MS = LMS (→ ref NCA) of the VHP
- Consensus approach
- Proposals:
  - CTFG to coordinate the CAP
  - Need IT tools improvements



# CAP issues

## ■ Scope

- Assessment activity under the CAP would benefit from to the current VHP
- Focus on what is today assessed by the majority of NCAs
- Questions on NCAs and ECs working together: timelines, complexity

## ■ 2<sup>nd</sup> wave process ?

## ■ Timelines

- OK 60 days (but some Sponsors require clock stop)
- But clock stop for ECs

## ■ CAP mandatory ?

- Optional for sponsors
- At least for a transitional period



# Conclusions

- **CAP/VHP will be/is a progress**
- **Even the most detailed CTD 2.0 / Guidance(s) will not be able to address all issues**
  - >>> case by case decisions by the concerned Member States should be possible
- **Active management by a Coordination is necessary to to make CAP/VHP a success**



# Thank you

