

# Voluntary Harmonisation Procedure

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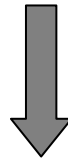
AGES Gespräch „Klinische Prüfung

14. Jänner 2010

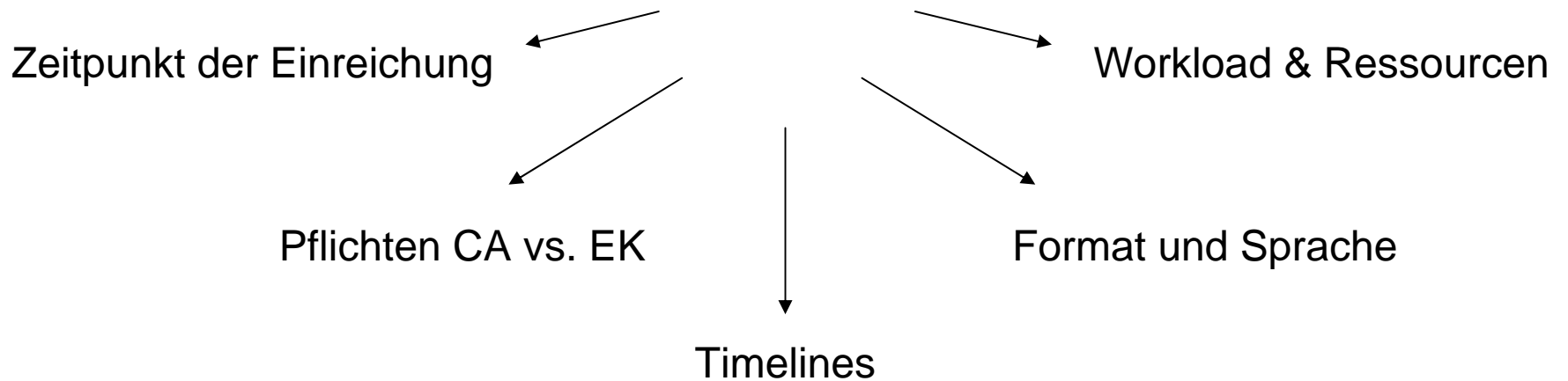


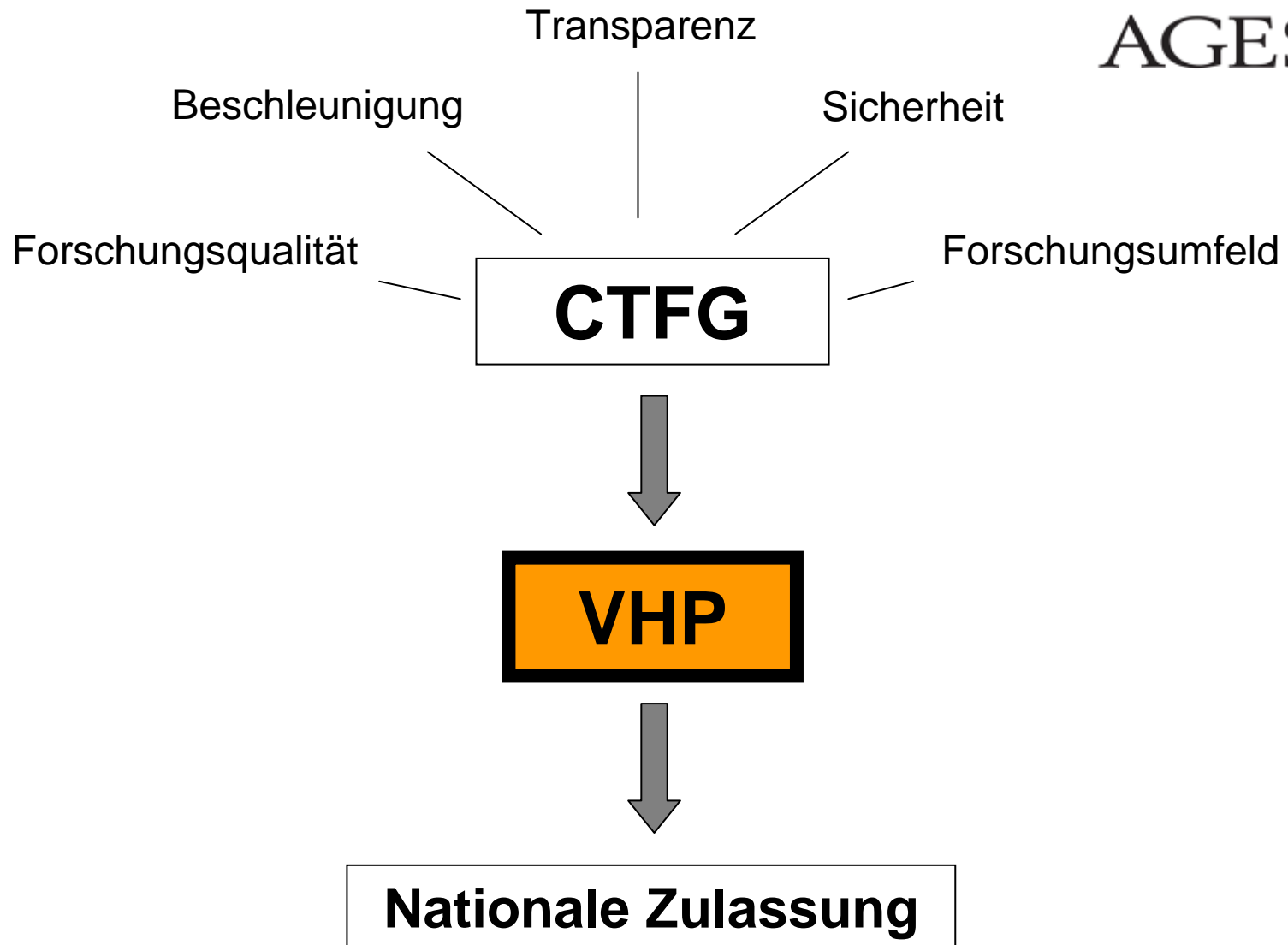


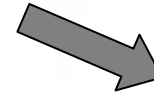
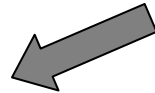
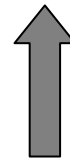
**Clinical Trials Directive  
2001/20/EC**



**Nationales  
Gesetz**







VHP Antragssteller



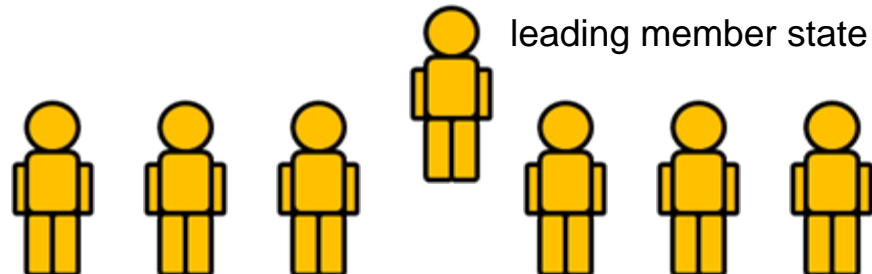
VHP Koordinator  
(VHP-C)



[VHP-CTFG@VHP-CTFG.EU](mailto:VHP-CTFG@VHP-CTFG.EU)



Teilnehmende Mitgliedsländer  
(P-NCAs)



neu seit 28.11.2009!

## ~~Antragsunterlagen~~

Covering  
Letter  
(inklusive  
EudraCT-Nr)

Antrags-  
formular  
(falls verfügbar)

Liste der  
NCAs

## ~~Studienunterlagen~~

Protokol  
(+ Synopsis)

Invest.'s  
brochure

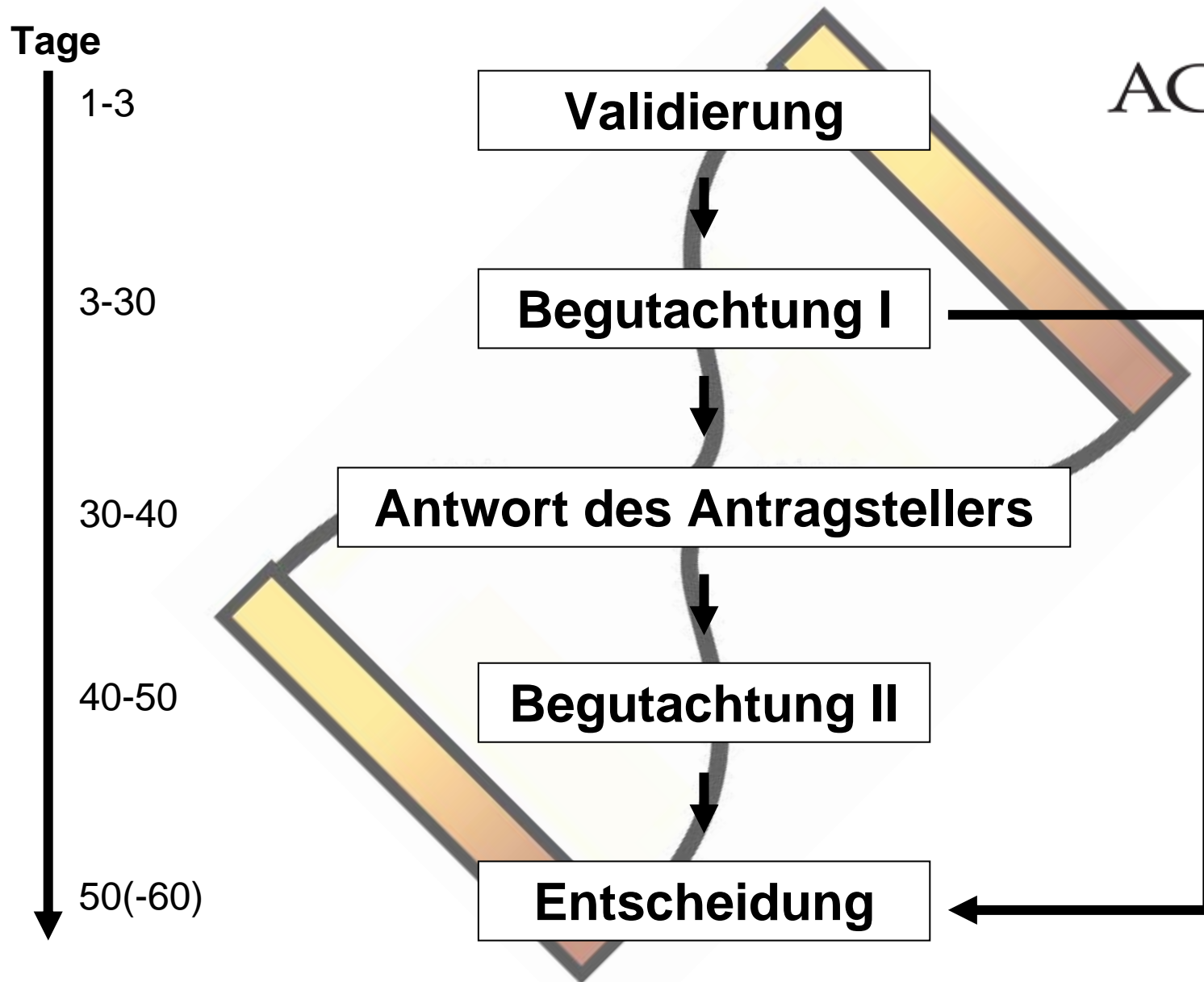
IMP  
folder

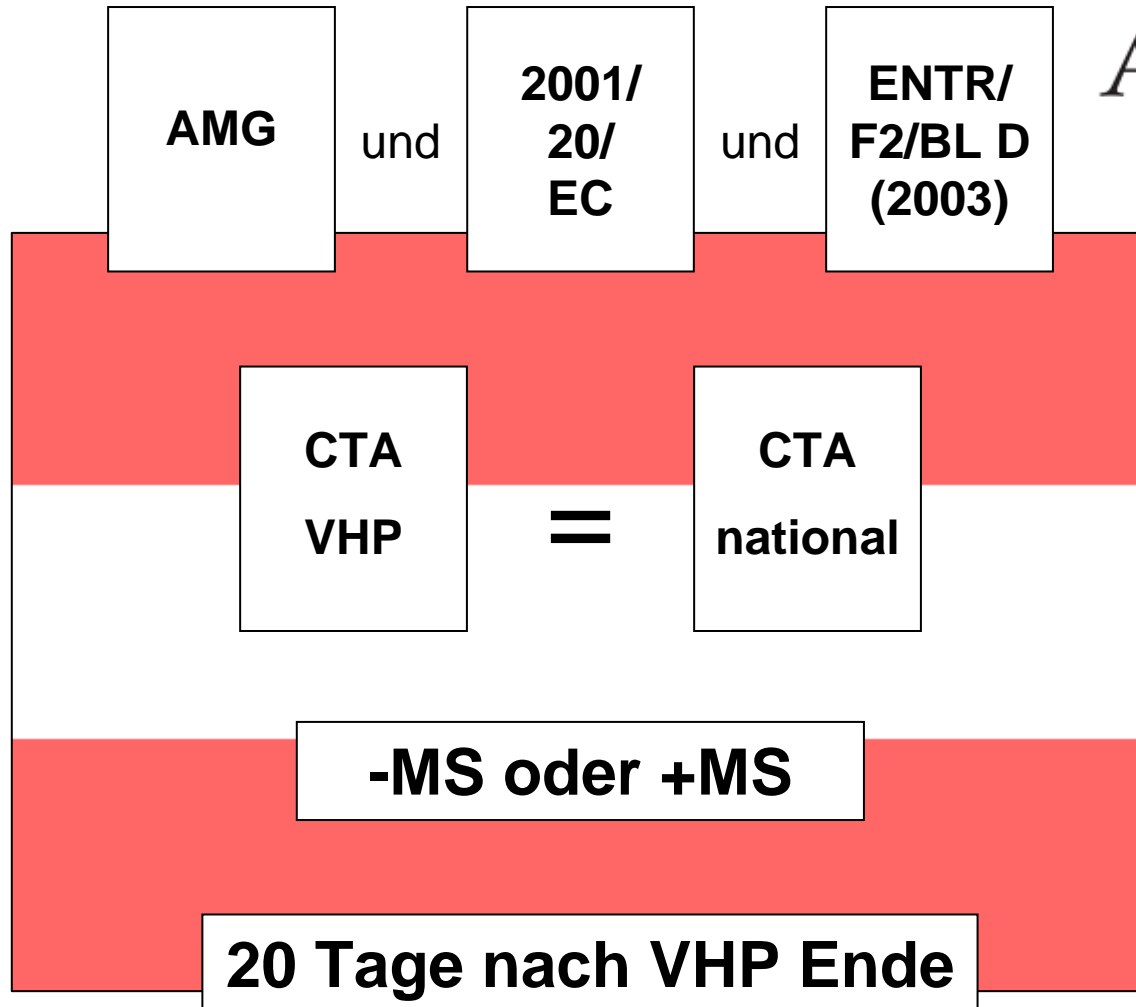
SA  
&  
PIP

**neu seit 28.11.2009!**



<b>Phase 1</b>	
Before 5th of each Month	Request for VHP
	Electronic submission of request to VHP-C
Around the 3rd Thursday	The VHP-C circulates the TC agenda, along with electronic copies of the LVHP and synopsis to all NCAs,
	Discussion of new request(s) during monthly teleconference (TC)
	If MN-CT eligible for VHP, Information of the applicant
<b>Phase 2</b>	
Day -7	VHP Draft CTA assessment step
	<b>Full electronic submission of the VHP dossier to the VHP-C by the applicant via E-Mail</b> <b>Acceptance to participate by Member States</b>

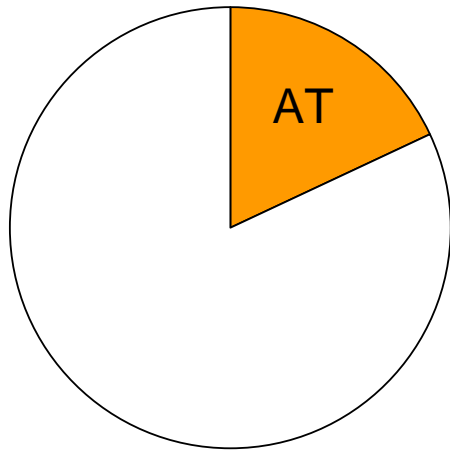




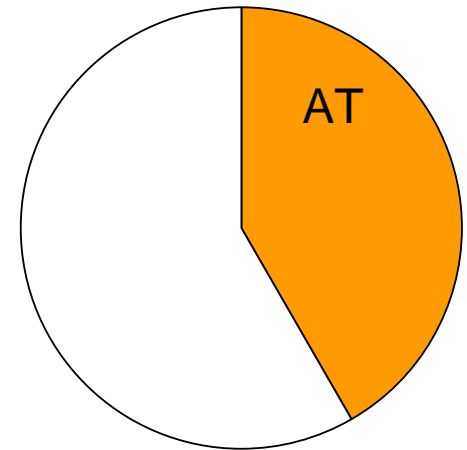
**Feedback!**

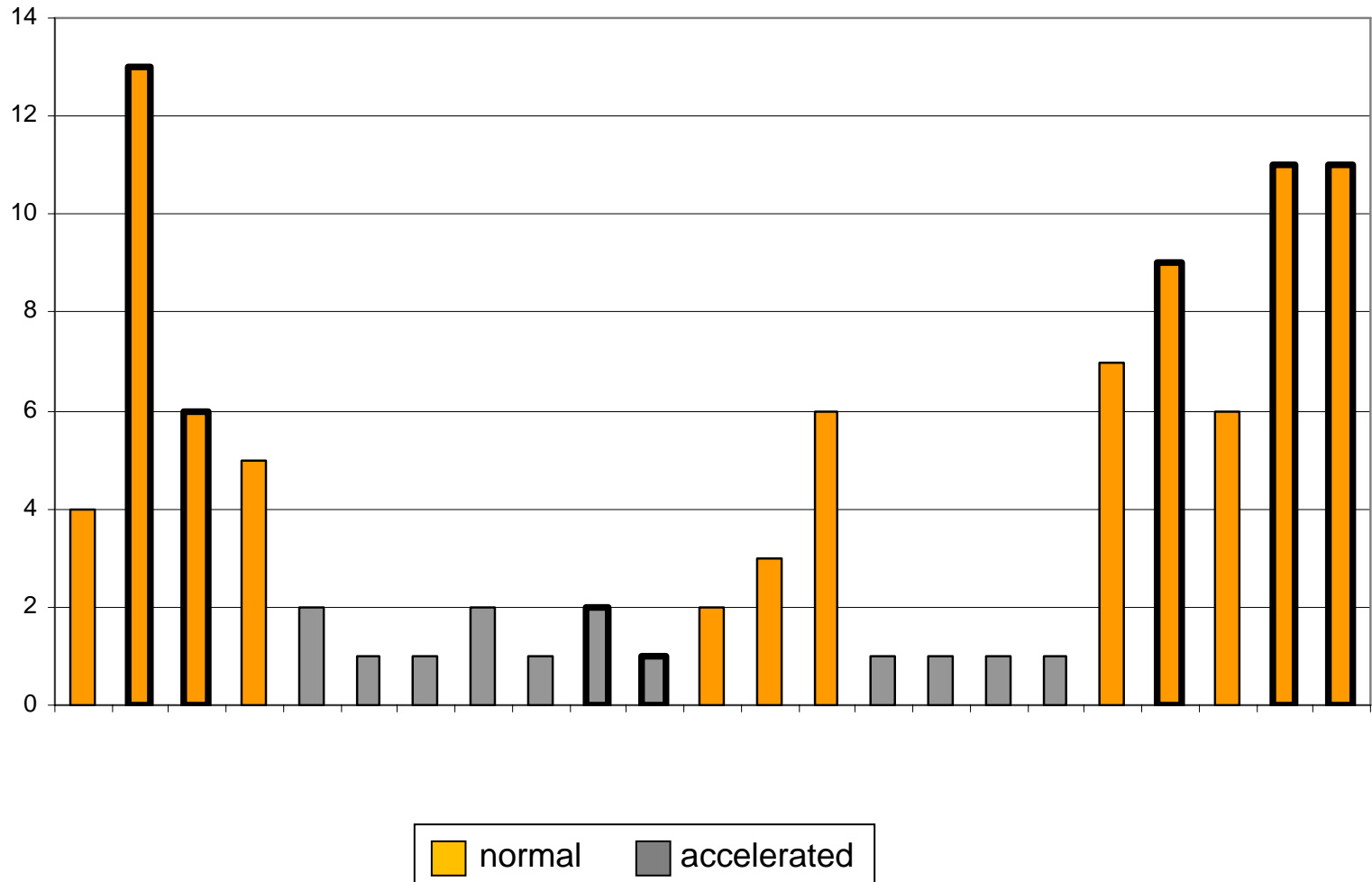
## 23 gestartete Verfahren

**11 „accelerated“  
(AT 2)**



**12 „normal“  
(AT 5)**





# Neues Guidance Document für Januar 2010!



Einschluss von  
Amendments

Ausweiten der  
Kriterien

Verkürzung der  
Antragsphase

Konsolidierung  
der GNA-Liste



Rapporteurs-  
prinzip?

einheitliche  
Reports?

„Harmonisierte“  
Zulassung?

**Danke für die Aufmerksamkeit!**



Ehrlich in seinem Arbeitszimmer