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European Clinical Trial Register— challenges from an academic perspective

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Is the information on a trial registry reliable?



Original Investigation | Statistics and Research Methods

Reliability of Trial Information Across Registries for Trials
With Multiple Registrations
A Systematic Review

Agreement of trial characteristics:

- 90% Sponsor
- 78% Primary outcome
- 63% Target sample size
- 46% Trial status

197 RCTs registered in more than 1 registry (e.g. EudraCT and Clinicaltrials.gov)

→ Interviews with Clinical Trial Registry Representatives







- Some efforts to harmonise trial registries ongoing (e.g. meetings organised by the WHO)
- Main hurdle for better harmonisation: Different legislation requirements
- Lack of regular updates to all trial registries assumed to be the main reason for the inconsistencies between trial registries

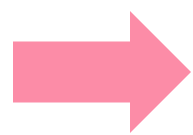
Specific for EudraCT

- Updating information does not seem to be common (user-friendliness?)
- No history of changes available
- Different entries for participating countries (reliability?)

Disease:	
Population Age: Adults, Elderly	Gender: Male, Female
Trial protocol: FR (Completed) ES (Completed) BE (Completed) DE (Completed) GB (Completed) PL (Prematurely Ended) IT (Completed)	
Trial results: View results	

Further aspects from our meta-research

	Clinicaltrials.gov	EudraCT
Availability of full trial protocols	42% (137/332) 	 ?
Statement about sharing individual patient data	 optional	 ?
Specific features for new adaptive designs/platform trials (e.g. start and end date, status, and samples size for individual arms)		



- Meta-research relevant to improve research process
- Burdensome process (manual extraction in duplicate); export function needed
- Important to assess how trial registries can provide useful and reliable information