

# *Clinical trial data: present & future*

## *An academic perspective*

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Utrecht University

Pharmacoepidemiology  
and Clinical Pharmacology



# Clinical trial data

Research Article


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## Publication rates and reported results in a cohort of gene- and cell-based therapy trials

Delphi GM Coppens<sup>1</sup>, Helga Gardarsdottir<sup>1,2</sup>, Cornelis A van den Bogert<sup>1</sup>, Marie L De Bruin<sup>1,3</sup>, Hubert GM Leufkens<sup>1</sup> & Jarno Hoekman<sup>\*,1,4</sup>

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Published: December 14, 2016 • <https://doi.org/10.1371/journal.pone.0167709>

PlosOne 2013

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**Mainly focusing on knowledge sharing & transparency – sharing of clinical trial results**

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RESEARCH ARTICLE

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Pharmacoepidemiology  
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**But also very useful for:**

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### But also very useful for:

- Information on regulatory decision making in relation to evidence from clinical trials
- Clinical endpoints

ORIGINAL ARTICLE | VOLUME 89, P199-208, SEPTEMBER 2017  Download Full Issue

## Primary endpoint discrepancies were found in one in ten clinical drug trials. Results of an inception cohort study

Cornelis A. van den Bogert • Patrick C. Souverein   • Cecile T.M. Brekelmans • ... Gerard H. Koëter • Hubert G.M. Leufkens • Lex M. Bouter • [Show all authors](#)

Published: May 20, 2017 • DOI: <https://doi.org/10.1016/j.jclinepi.2017.05.012> •  Check for updates

# ***Remote Trial Elements Reported in Publicly Available Clinical Trial Protocols***



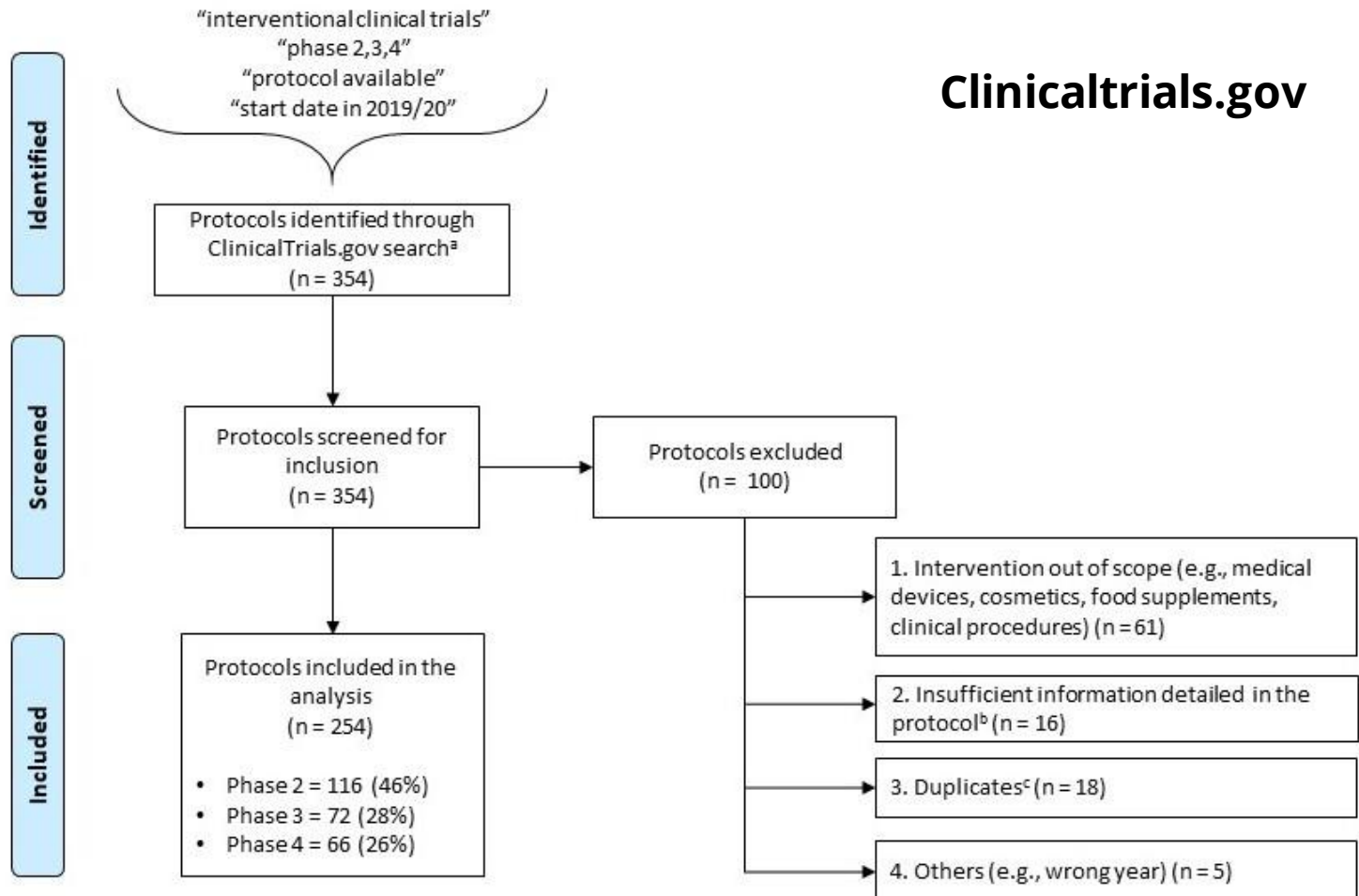
# Methodology

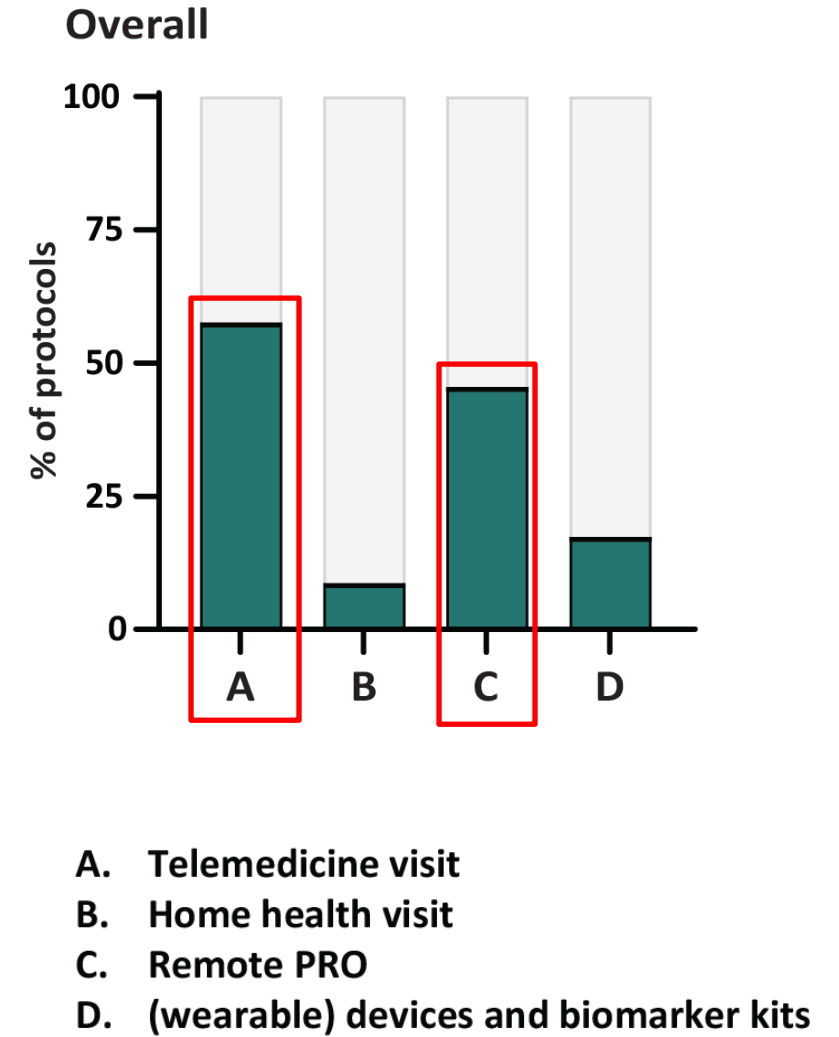
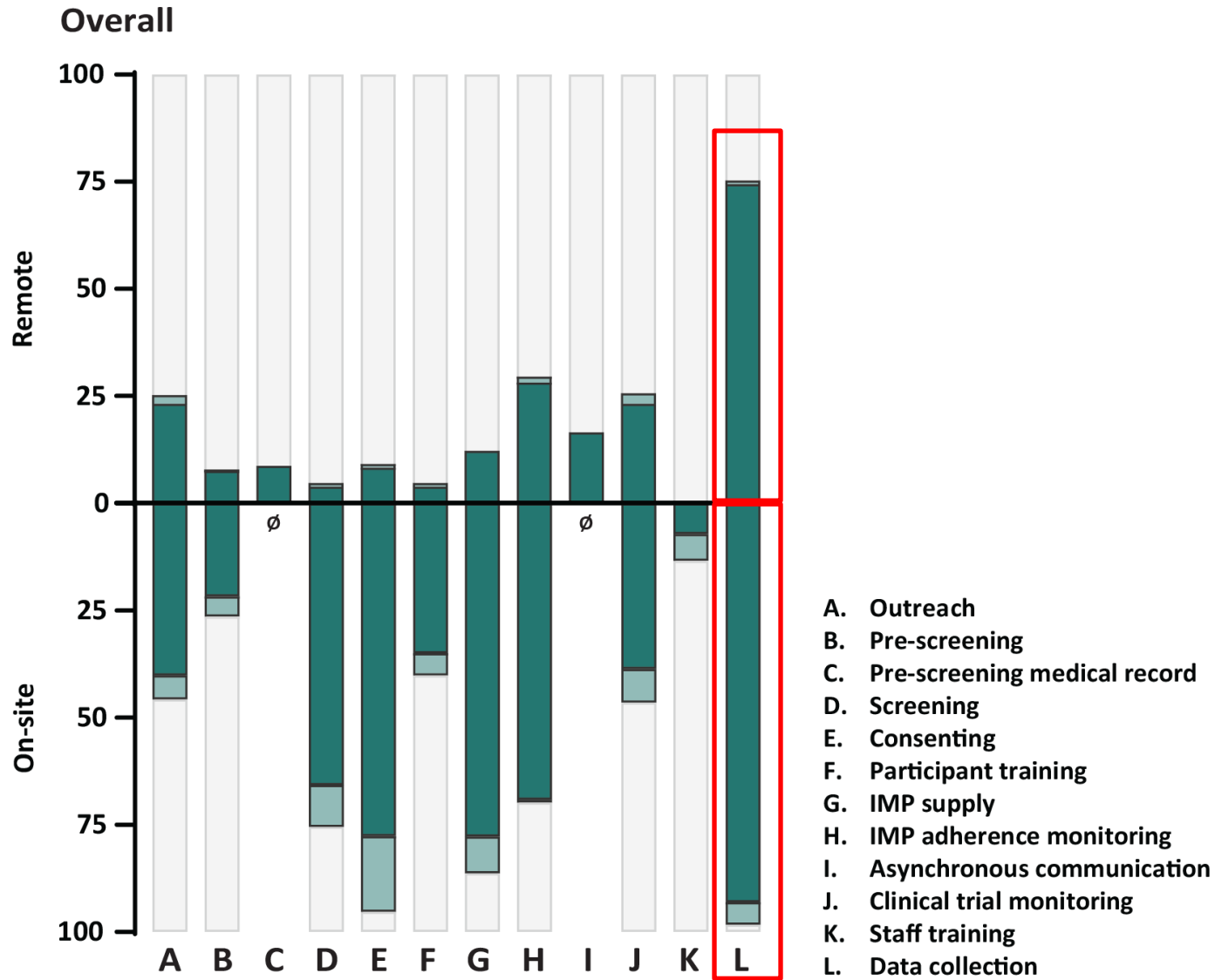
## Remote element

*'Operational trial activities that take place outside the investigator site'*



Clinicaltrials.gov



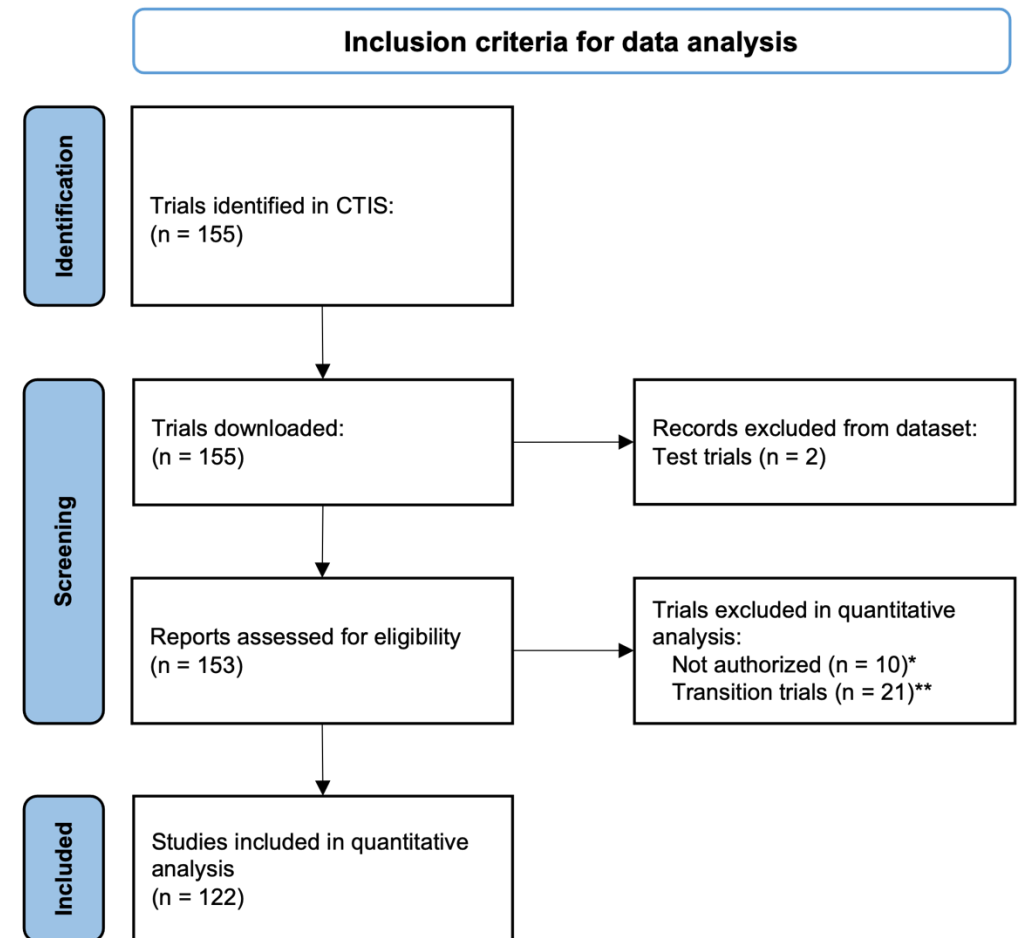


***Low-intervention clinical trials in Europe:  
investigating the characteristics and  
sponsor experiences***



# Methodology

- **Low interventional clinical trials**  
(article 2.2 of CTR EU 536/2014 CTR)
- Clinical Trial Information System  
(CTIS)
- Data extraction on 21 April 2023

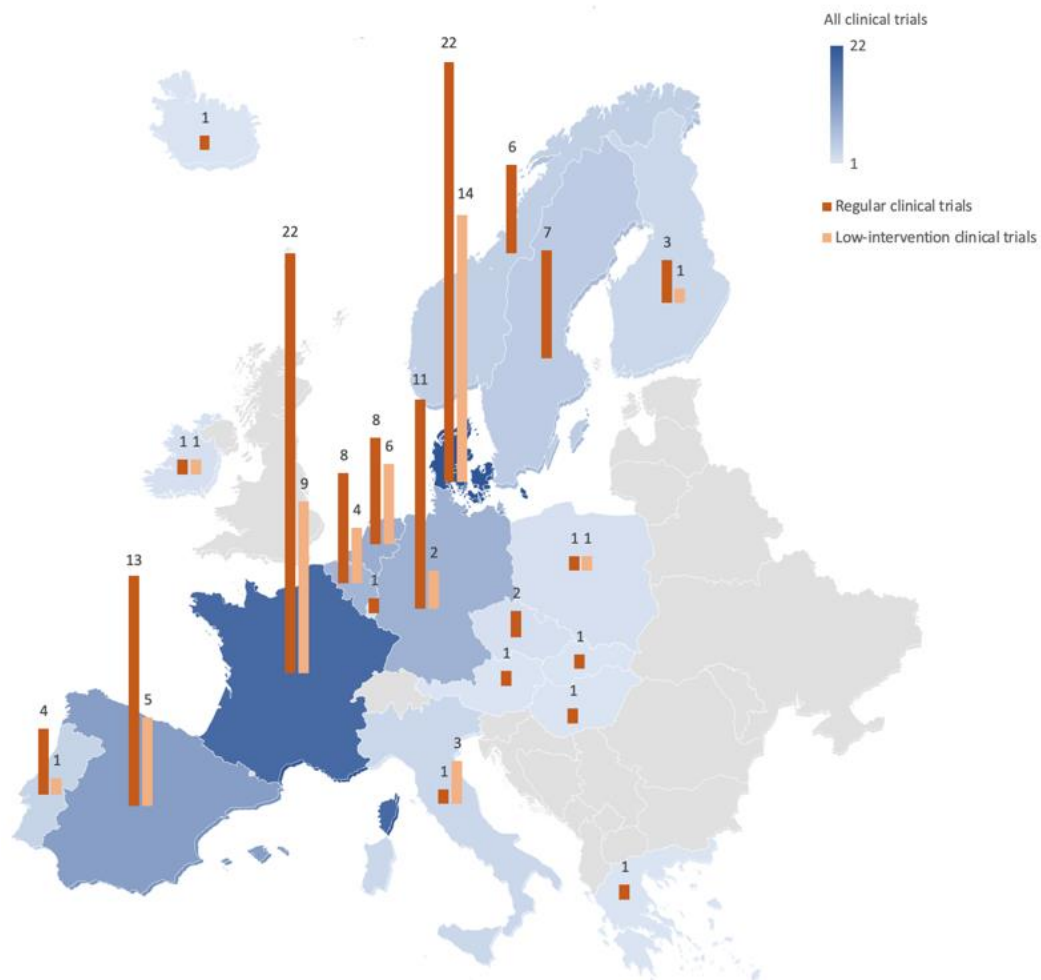


\*Trials authorized in at least one country are included.

\*\*Transition trials: trials that were submitted under the CTD as well.



### Distribution of identified clinical trials in Europe (CTIS, April 2023)



	Clinical trials		LIMC
	Investigator (N=66)	Industry (N=18)	Investigator (N=38)
<b>Participants</b>			
Number of participants	80 (40-260)	96 (66-200)	320 (180-880)
Follow up (weeks)	29 (12-55)	40 (11-89)	48 (12-100)
<b>Therapeutic area</b>			
Cancer (C04)	10 (15.2%)	4 (22.2%)	3 (7.9%)
Cardiovascular (C14)	8 (12.1)	1 (5.6%)	8 (21.1%)
<b>Clinical trial characteristics</b>			
Study phase IV	12 (18.2%)	0 (0.0%)	31 (81.6%)
Multi-site trials	33 (50.0%)	11 (61.1%)	26 (68.4%)
Multi-country	7 (10.6%)	8 (44.4%)	3 (7/9%)

**Thank you!**

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