

Publication Rates of Clinical Trials in DME

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Summary slide

- 61.9% of registered clinical trials in DME (2005-2015) were eventually published in the peer reviewed literature

Background

- A significant number of clinical trials have investigated treatments for DME
- Results can be difficult to obtain
 - Many are not published or archived in a searchable data set

Background

- Inability to identify critical design and outcome measures may lead to:
 - Repetition of a failed investigation
 - R&D on assets that have known liabilities
 - Inability to best design subsequent studies

Purpose

- We have previously analyzed the publication rate of trials concerning NVAMD from 1998-2009
- 54% publication rate

Purpose

- Determine the publication rate of registered clinical trials evaluating therapeutic approaches for DME
- Evaluate investigations from 2005-2015
- Did we improve?

Methods

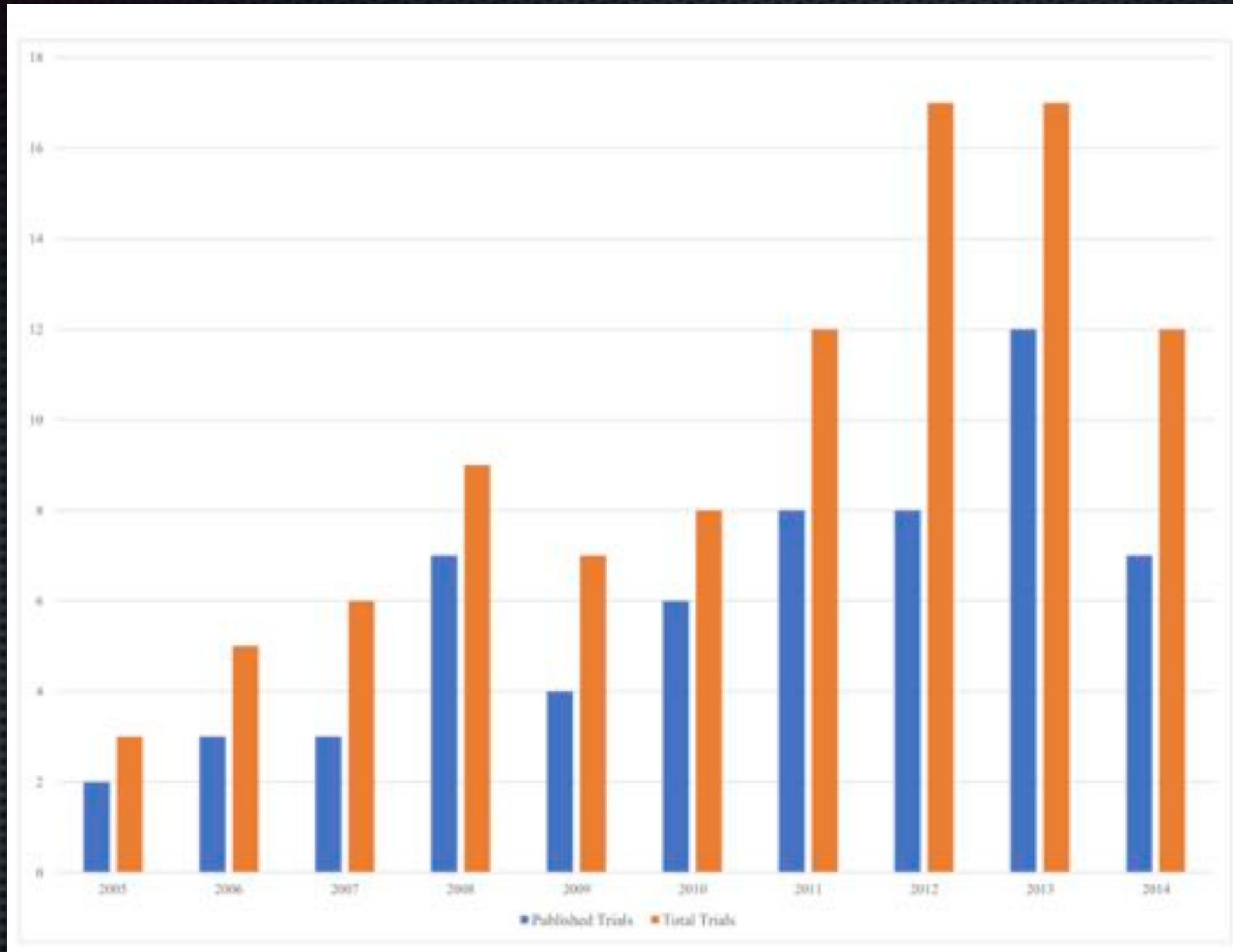
- Studies were identified by searching for DME on [ClinicalTrials.gov](https://clinicaltrials.gov) from 2005 to 2015
- End date allowed for adequate time for analysis and publication by the time of this study
- Non interventional, terminated, and incomplete trials were excluded

Methods

- Publication status of was determined by searches of PubMed.gov and Google Scholar
 - Title
 - Keywords
 - Authors
 - NCT number
- Publication rate was calculated

Results:

- 247 trials were initially identified
 - 97 met inclusion criteria
- Increasing number of trials in later study years



- Trials and publications per annum (2005-2015)

Results:

- Primary endpoint (publication rate)
 - 61.9%

Results: secondary analysis

- No impact on publication rate:
 - Trial location (domestic vs. international)
 - Date of completion (2005-09 vs. 2010-15)
 - Funding source (industry vs. grant/investigator)
 - Non-industry > Industry
 - 68% vs. 57%, $p=0.26$

Results: secondary analysis

- Later phase trials (II/III-IV) were published at a higher rate compared to early phase trials (I-II)
 - 74.5% vs. 50%, $p=0.01$

Conclusion

- Despite advances in processes to encourage the publication and impact of clinical trials, only 61.9% of trials in DME were published

Conclusion

- Difficult to quantify the impact
- Publication of studies can be difficult:
 - Negative data is a challenge
 - Enthusiasm for publication can be reduced as investigative programs move forward or data is negative

Conclusion

- Inability to obtain results may lead to:
 - Duplication of experimental approaches
 - Inability to recognize asset performance
 - Inefficiencies in resource allocation
 - Patients may be put at risk

Conclusion

- Starting in 2017, results have been required to be listed on [ClinicalTrials.gov](https://clinicaltrials.gov)
 - Abbreviated format
- Impact of this is yet to be determined