# Impact of ICMJE Trial Registration Policy at 20 Years

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## Background

The 2004 International Committee of Medical Journal Editors (ICMJE) policy required prospective registration of clinical trials as a condition for publication. Prior work reported widespread inconsistencies at earlier time points, including incomplete registration, retrospective or unregistered trials, and discrepancies between registered and published primary outcome measures.

## Objective

This cross-sectional analysis aims to build on previous work, now 20 years post-ICMJE policy, and expands to include the global landscape of trial publication and registration.

## Design

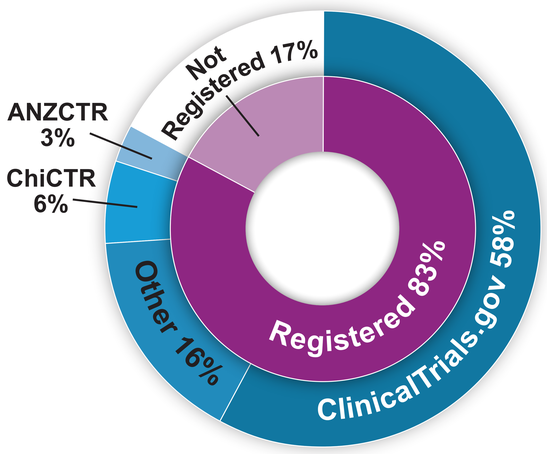
We assessed a convenience sample of primary trial results publications first indexed in PubMed from July to September 2024 that was randomly selected by funding category to reflect a distribution of 40% industry and 60% non-industry. The journal title, first publication date, and any unique identifier from an ICMJE-recognized registry listed in the abstract or body text were extracted from manual review. Publications without trial registry information had their status confirmed via advanced search within the WHO International Clinical Trials Registry Platform (ICTRP).

From a random subset of 100 sampled publications listing registry identifiers, again selected randomly for a 40%-60% funding distribution, we extracted first registration and study start dates from corresponding registration records to determine timing of registration (prospective or retrospective) and compared primary outcome measures (POMs) listed in publications and records.

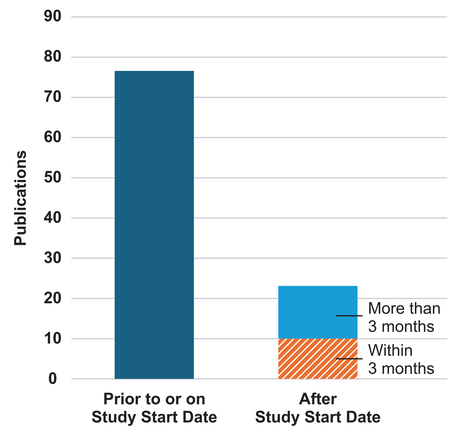
## Characterization of Subset of Primary Trial Results Publications by Funding Source (N=100)

| Attribute | Number (% Total) by Funding Source | | |
|---|---|---|---|
| **Timing of Registration** | **Industry (N=40 Publications)** | **Non-industry (N=60 Publications)** | **Total (N=100 Publications)** |
| **Prior to or on Start Date** | 33 (82.5%) | 44 (73.3%) | 77 (77.0%) |
| **After Start Date** | 7 (17.5%) | 16 (26.7%) | 23 (23.0%) |
| **Within 3 months of Start Date** | 4 (57.1%) | 6 (37.5%) | 10 (43.5%) |
| **More than 3 months after Start Date** | 3 (42.9%) | 10 (62.5%) | 13 (56.5%) |
| **Comparison: Published and Registered Primary Outcome Measures (POMs)** | **Industry (N=53 POMs)** | **Non-Industry (N=82 POMs)** | **Total (N=135 POMs)** |
| **Concordant** | 41 (77.4%) | 66 (80.5%) | 107 (79.3%) |
| **Discordant** | 12 (22.7%) | 13 (15.9%) | 25 (18.5%) |
| **Not Registered** | 8 (66.7%) | 5 (38.5%) | 13 (52.0%) |
| **Registered as Secondary Outcome Measure** | 1 (8.3%) | 6 (46.2%) | 7 (28.0%) |
| **Registered as POM with Different Time Frame** | 3 (25%) | 2 (15.4%) | 5 (20.0%) |
| **Unclear – Registered POM Vague** | 0 (0%) | 3 (3.7%) | 3 (2.2%) |

## Registration Status of Sampled Publications (N=434)




## Timing of Registration of Subset (N=100)




## Results

Of 434 overall sampled articles from 322 journal titles on October 17, 2024, 82.7% (359/434) disclosed registration identifiers, of which 212 (59.1%) were listed in abstracts. Of 17 represented registries, ClinicalTrials.gov (69.6% [250/359]), ChiCTR (7.0% [25/359]), and ANZCTR (3.6% [13/359]) were cited most frequently.

Among the subset of 100 trials, 23% were retrospectively registered. Among the extracted 135 POMs, 2.2% (3/135) were coded as unclear and 18.5% (25/135) as discordant: 52.0% (13/25) due to published POMs missing from registration records and 28.0% (7/25) due to published POMs registered as secondary outcome measures.

## Conclusion

These findings do not differ widely from previous work of 10 years ago and no substantive differences between trials funded by industry and non-industry sources were observed. Findings suggest that the policy goals of full transparency and accountability through trial registration have yet to be reached.

## Acknowledgments

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