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Inconsistent ethics reporting in individual participant data meta-analyses: a call for updating PRISMA and PRISMA-IPD

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Abstract

Background Interest in performing individual participant (or patient) data meta-analysis (IPD-MA) from randomized controlled trials (RCTs) has increased in recent years. With our PubMed search approach which considered only the titles of the articles and was conducted in October 2025, the first IPD-MA was published in 1998, whereas 198 were published in the first 9 months of 2025. Researchers use PRISMA 2020 and, above all, PRISMA-IPD to report the results of these studies.

Main text There are five ethics items—which are not included in either PRISMA 2020 or PRISMA-IPD—that are inconsistently included in the IPD-MA published in prominent medical journals, as shown in a sample of 19 IPD-MAs published in top general/internal medicine journals between January and September 2025. Two items refer to the RCTs included in the meta-analysis, i.e., whether approval from a research ethics committee (REC) was obtained, and whether participants of those trials provided informed consent. The other three items refer to the IPD-MA itself, i.e., whether it was approved by an REC, what the de-identification status was for the data (i.e. pseudonymized vs. anonymized), and whether the participants in all the trials included in the meta-analysis had given their consent or had not objected to the secondary use and sharing of their data with third parties.

Conclusions Due to their relevance, readers should be informed about these five items in the text of the IPD-MA or, as an alternative in certain cases, in the disclosure section of the IPD-MA published report. Specifically, the two items of information concerning the trials included in the IPD-MA should be included in an updated PRISMA 2020. All five items should be included in the next update of the PRISMA-IPD.

Keywords PRISMA, PRISMA-IPD, Ethics, Informed consent, De-identified, Anonymized, Pseudonymized, Data

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There is an increasing interest in conducting individual participant data meta-analysis (IPD-MA) from randomized controlled trials (RCTs). A search on PubMed performed on October 6, 2025, for articles containing 'individual participant data meta-analysis' or 'individual patient data meta-analysis' in the title returned 671 and 811 articles, respectively, starting with one in 1998 and concluding with 198 in the first 9 months of 2025. Yet, these 1,482 articles only represent 0.6% of the 236,000 articles with meta-analysis in the title available in PubMed. The interest in IPD-MA stems from the fact that IPD-MA are potentially more reliable than meta-analyses based on aggregate data [1] providing a more comprehensive assessment of risk of bias and in data integrity checks, and more detailed and flexible analyses [2, 3]. So, for example, IPD-MAs allow for exploring moderators based on patients' characteristics, while in aggregated data meta-analyses this is prone to ecological fallacy. However, IPD-MA are more complex to perform than aggregate data meta-analyses, as they require qualified personnel to obtain, manage, and analyze the data, and are more expensive and time consuming [2]. There is hope that IPD-MAs could help better individualize treatments; yet, in practice it is less clear [4].

De-identified, pseudonymized, and anonymized participant data

Participants in clinical trials have the right to know how their personal data will be used [5]. An IPD-MA is based on re-using the IPD from two or more trials with data that are either pseudonymized (i.e., participants could be identified) or anonymized (i.e., it is impossible to identify any participant) [6, 7]. Such data are often described as "de-identified" but used with different technical and legal meanings [6]. Even within the same country definitions of "de-identification" differ as happens in the USA [8]. So, "de-identified" is a term that should be avoided while "pseudonymized" or "anonymized" are more adequate when describing the type of IPD used in a given IPD-MA. In clinical trials, participant-level data are typically pseudonymized. Where possible, the use of pseudonymized data is preferred for IPD-MA rather than anonymized data [2, 7]. However, anonymized IPD are more frequently available, especially from industry-sponsored trials (e.g., data provided through Vivli or Clinical Study Data Request). When it is difficult for the trial data custodian to classify the data as pseudonymized or anonymized, the authors of the IPD-MA may refer to the source and access mechanism (e.g., "shared directly by trialists"), which would itself be informative.

Reporting of research ethics items in individual participant data meta-analyses

It is common that IPD-MAs published in high impact journals are reported following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [9] checklist or the more specific PRISMA-IPD checklist [10]. The current versions date from 2015 (PRISMA-IPD) and 2020 (PRISMA). Both checklists comprise 27 items though none directly address ethical and other aspects relevant to the type of IPD used to conduct the meta-analysis.

Here we will discuss five relevant aspects regarding either the underlying RCTs or the IPD-MA itself. Critical information regarding the underlying RCTs in the meta-analysis includes (1) whether approval from a research ethics committee/institutional review board (REC/IRB) was obtained and (2) whether participants of those trials provided informed consent. Critical information regarding the IPD meta-analysis itself includes information on (3) whether it was approved by a REC/IRB, (4) what the de-identification status was for the data (i.e. pseudonymized vs. anonymized), and (5) whether the participants in *all* the trials included in the meta-analysis had given their consent or had not objected to the secondary use and sharing of their data with third parties. Without consent or proven lack of objection, researchers must have had implemented measures such as the IPD-MA protocol approval by the relevant REC/IRB, greater restriction on data access or even upgrading the level of de-identification from pseudonymization to anonymization [5, 7]. This aspect is particularly important because data confidentiality, plans for secondary use and sharing are poorly described in most clinical trial informed consent documents [11]. This information would allow readers to understand the degree of respect that IPD-MA investigators have shown for the consent given by participants in the included trials, as well as the measures taken by investigators to conform to the specific consents [12].

What IPD-MAs recently published articles report concerning research ethics items

To explore current reporting practices around IPD, we manually assessed IPD-MAs of RCTs published in 20 high impact general/internal medicine journals (as per Journal Citation Reports 2024 impact factor) between January and September 2025 (Supplementary material). Table 1 shows the reporting of the five relevant aspects of IPD-MA mentioned above, none of which are included in the PRISMA 2020 or PRISMA-IPD checklists. Eleven of 19 IPD-MAs reported on REC/IRB approval of the trials included, and 11 provided information on whether participant informed consent had been obtained. Of IPD-MA protocols, only 6 reported REC/IRB review, including whether approval was granted ($n=4$), or

Table 1 Information reported in articles[a] describing individual participant (or patient) data meta-analysis of randomized controlled trials published in high impact general/internal medicine journals, January–September 2025

Reference (Country)[b]	No. of trials included	Information regarding the trials included in the IPD-MA		Information regarding the IPD-MA		
		REC/IRB approval	Participants' informed consent granted	REC/IRB approval (Country)[c]	Type of IPD	Participants consented the reuse of their IPD by third parties[g]
Dehbi et al.; Lancet 406: 43 (UK)[d]	4	Reported	Reported	Not reported	Pseudonimized	Not reported
EBCTCG; Lancet 406: 603 (UK)[d]	12	Not reported	Not reported	Not reported	Not reported	Not reported
Giacoppo et al.; BMJ 389: e082561 (Switzerland)[d]	5	Reported	Reported	Not required	Anonymized	Not reported
Guo et al.; Lancet 406: 1009 (China)[e]	6	Not reported	Not reported	Granted (China)	De-identified	Not reported
Hughes et al.; BMJ MED 4: e000877. (Australia)[d]	17	Not reported	Reported	Granted (Australia)	De-identified	Not reported
Hunter et al.; Lancet 406: 1235 (Australia)[d]	17	Not reported	Not reported	Granted (Australia)	De-identified	Not reported
Knowlton et al.; Plos Med 22:e1004616. (USA, UK)[e]	6	Reported	Reported	Not reported	Not reported	Not reported
Lee et al.; Ann Intern Med 178: 533 (China, South Korea)[d,e]	3	Reported	Reported	Not reported	Anonymized	Not reported
Liu et al.; eClinMed 84, 103,279. (USA)[d]	8	Reported	Not reported	Not reported	Not reported	Not reported
Luo et al.; JAMA Intern Med 185:572 (USA)[d]	14	Reported	Reported	Not reported	De-identified	Not reported
Mismetti et al.; Eur J Intern Med 131: 65 (France)	2	Not reported	Not reported	Not reported	Not reported	Not reported
Nogueira et al.; Lancet 405:61 (China, Netherlands)[d,e]	4	Reported	Reported	Not reported	Anonymized	Not reported
Roh et al.; eClinMed 83, 103,202; (USA)	6	Not reported	Not reported	Not reported	Not reported	Not reported
Rosello et al.; Lancet 406: 1128 (Spain)	4	Reported	Reported	Not reported	Not reported	Not reported
Valgimigli et al.; Lancet 406: 1091 (Switzerland)[d]	7	Reported	Reported	Not reported	Anonymized	Not reported
Vanheer et al.; Plos Med 22: e1004683 (Netherlands)[f]	6	Reported	Reported	Not reported	Not reported	Not reported
Wang et al.; Plos Med 22: e1004523 (USA)[f]	11	Not reported	Not reported	Waived (USA)	De-identified	Not reported
Wightman et al.; Plos Med 22: e1004553. (UK)[f]	34	Not reported	Not reported	Granted (UK)	Not reported	Not reported
Zannad et al.; Lancet 406: 1351 (France)	2	Reported	Reported	Not reported	De-identified	Not reported

IPD Individual participant (or patient) data, *IRB* Institutional review board, *MA* meta-analysis, *REC* research ethics committee

[a] In the text and/or disclosure section

[b] Country of the corresponding author

[c] Country of the REC/IRB involved

[d] Report having followed PRISMA-IPD checklist

[e] There are two corresponding authors in this article

[f] Report having followed PRISMA checklist

[g] It should be noted that, in the case of some of these IPD-MAs (such as those with anonymized data in certain jurisdictions or those for which approval was obtained from an REC/IRB or which were exempted from review) it would be understandable if this hadn't been reported

waived ($n=1$) or review was not required ($n=1$); 13 did not report on this topic. With regards to the type of IPD, 11 mentioned that 'anonymized' ($n=4$), 'pseudonymized' ($n=1$) or 'de-identified' ($n=6$) data were used in their analyses.

None of the 19 IPD-MAs report on whether the participants in all the trials included in the meta-analysis had given their consent or had not objected to the secondary use and sharing of their data with third parties. It is difficult to speculate why none of the 19 IPD-MAs reported on consent for secondary use, but possible explanations include that secondary use was covered by the original trial consent (for example, through broad consent provisions), but trialists forgot to report it to the authors of the IPD-MA or the authors forgot to report it in the IPD-MA article; reliance on data-sharing agreements or governance frameworks from established platforms, which may be considered sufficient to address

consent-related issues; and the use of anonymized datasets, for which additional consent requirements may not apply under some regulatory frameworks. It is also possible that, because reporting on consent for secondary use is not yet standard practice, it is given limited attention by authors. In this respect, an analysis of 240 participant information sheets/informed consent forms from trials conducted in Ireland and the UK showed that only 28% stated that data could be shared with other researchers [11].

It should be highlighted that only three IPD-MAs did not report on any of these five aspects. REC/IRB approval of the IPD-MA protocol is not always necessary, as happens in many jurisdictions when anonymized IPD are used [5]. In one of the IPD-MAs with anonymized data authors referred that REC/IRB protocol approval was 'not required'; yet, in the other three IPD-MAs with anonymized data the authors did not report on this. These findings should be interpreted with caution, as they refer to a specific time period and certain journals (eight of the 19 were from *The Lancet*); therefore, a broader analysis might yield different results.

The applicability of the proposed reporting items varies across regulatory contexts, as requirements for secondary analyses of IPD are not uniform. For example, under the EU General Data Protection Regulation, analyses of fully anonymized data allow for open data sharing and do not even require informing participants about reuse, whereas pseudonymized data typically require participant information and the right to object to the re-use. Other jurisdictions, such as those governed by the US Common Rule, apply different criteria. Data accessed through industry platforms may also be subject to specific governance frameworks. Investigators should therefore specify the jurisdiction(s) of both the original trials and the secondary analyses, and clarify compliance with the relevant ethical, legal, and governance requirements.

Due to their relevance, readers should be informed about these five aspects of the IPD-MA in the text of the article. The IPD-MA disclosure section could be an alternative in certain cases, such as when different information from many trials must be provided, which would make the article text difficult to read. The fact that IPD-MA authors are already at least partially reporting on these ethical aspects, suggests that they are recognized as relevant, despite these items not being included in either the PRISMA 2020 or the PRISMA-IPD.

Update PRISMA 2020 and PRISMA-IPD to strengthen transparency

There is still a long way to go before most stakeholders ask authors to report on data-sharing and management plans, which should consider the five items discussed above. While 80% of journals specified a data-sharing policy, this only happened in 42% of professional research organizations (e.g., nonprofits, governmental organizations, professional societies), and only 32% of pharmaceutical companies included a data-sharing policy on their websites [13]. Trialists are not good at sharing their data [14]. There is a lack of trained personnel to fulfil sharing requests of de-identified or anonymized IPD [15]. This suboptimal situation is exacerbated by the fact that it has recently become apparent that there are no well accepted guidelines on how to conduct studies involving the secondary use of clinical trials data [16]. Ultimately, a lack of IPD sharing reduces post-trial IPD-MA efforts and examining reproducibility, a continued problem across disciplines [17].

Funders and journal editors should require authors to report on these five items. Otherwise, we will continue to find inconsistencies in the reporting of this type of information, even within the same journal, as can be seen in the cases listed in Table 1 from *eClinical Medicine*, *Plos Medicine*, and *The Lancet*. IPD-MAs are usually funded. In our sample, 15 of the 19 IPD-MAs included in Table 1 reported receiving external funding. Journals should ask IPD-MA authors to report their findings using PRISMA-IPD, rather than PRISMA—as three articles in Table 1 did. However, it would be important for future updates of these guidelines to explicitly include the requirement to report the two trials' elements in PRISMA 2020—which are included in SPIRIT 2025 statement [18]—and the five elements (two from the trials and three from the meta-analysis itself) of the research analyzed in this article in PRISMA-IPD. It is necessary to report whether approval was obtained from the relevant RECs/IRBs and whether informed consent was obtained from participants in *all* trials included in any meta-analysis, including those that use aggregated data from the trials. This allows the reader to know whether the meta-analysis data are based on trials that have met the minimum requirements for research ethics involving humans.

Strengthening transparency in these areas would promote more consistent and ethically sound reporting practices across journals and research groups. Until such guidance is formally adopted, we should expect inconsistencies in how these issues are documented will persist, limiting readers' ability to assess the ethical integrity and data provenance of IPD-MAs. Expanding the PRISMA 2020 and PRISMA-IPD framework to address these dimensions would represent an important step toward improving reproducibility, accountability, and respect for participants whose data underpin this increasingly influential form of evidence synthesis.

Abbreviations

IPD	Individual participant data
IPD-MA	Individual participant data meta-analysis
IRB	Institutional review board

PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PRISMA-IPD	Preferred Reporting Items for Systematic Reviews and Meta-Analyses-Individual participant data
RCTs	Randomized controlled trials
REC	Research ethics committee
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials

Supplementary Information

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Supplementary Material 1

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RDR led the conceptualization, conducted the search and wrote the first draft. FN conducted the research and with the rest of authors provided comments and edits of subsequent drafts. All authors contributed to critically revising the article for important intellectual content. All authors read and approved the final manuscript and had final responsibility for the decision to submit for publication.

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Data availability
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