BePRECISE Checklist: reporting guidelines for precision medicine research

The checklist should be cited as follows: Lim SS, Semnani-Azad Z, Morieri ML, Ng AH, Ahmad A, Fitipaldi H, Boyle J, Collin C, Dennis JM, Langenberg C, Loos RJF, Morrison M, Ramsay M, Sanyal AJ, Sattar N, Hivert MF, Gomez MF, Merino J, Tobias DK, Trenell MI, Rich SS, Sargent JL, Franks PW. *Reporting guidelines for precision medicine research of clinical relevance: the BePRECISE Checklist*. Nature Medicine. 2024.

Item number		Item wording	Elaboration and Explanation of Item
***E. Equity, inclusion, diversity and patient and public involvement and engagement* (PPIE)**. Authors are encouraged to address these topics in their manuscripts within relevant sections. The reporting items listed herein are not exhaustive and all considerations of PPIE (including patient-reported outcomes and experience), as well as any community engagement efforts, should be described wherever possible.			
E1		Use appropriate population descriptors such as ancestry, geographic and sociodemographic characteristics of all participants, particularly those in underrepresented groups.	*In cases where data from underrepresented group(s) are collected, and the sub-sample size is n≥20, all data should be analyzed and reported (even in cases where subgroup analyses might be considered underpowered, as this will facilitate subsequent meta-analyses of results). A minimum sample size of 20 is based on the 'All of Us Research Program Data User Code of Conduct' (https://www.researchallofus.org/faq/data-user-code-of-conduct/), and is intended to avoid disclosing individual participant identity.* *Avoid merging sub-groups into larger heterogeneous groups (e.g., 'non-European ancestry').* *While there is ongoing discussion on the appropriate use of words and terms describing groups within populations, this Checklist yields to other guidelines*

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			on this matter. If data pertaining to race and/or ethnicity is collected this should be reported in accordance with relevant established guidance.
E2		Describe the implications of inclusion and/or exclusion of people who are understudied in precision medicine research or underserved by health services	*Describe implications for successful extrapolation of study findings to other groups, particularly those typically underrepresented in precision medicine research.*
E3		Describe PPIE in any aspect of the study design, conduct and/or reporting	*PPIE may include consultation, involvement, partnership, or leadership by end-users, including being part of the research and/or authorship team.*
E4		Where possible, and ideally with guidance from PPIE representatives, describe the potential impact of the study's results from a lived experience perspective, especially the impact of the research on people living with disease.	
1. Title and/or abstract			
1.1		Include 'precision medicine' in the title or abstract	*These reporting guidelines use the terms 'precision medicine' and 'personalized medicine', defined elsewhere (Tobias D.K., et al. Nat Med. 2023), as follows:*

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			"Precision medicine focuses on minimizing errors and improving accuracy in medical decisions and health recommendations. It seeks to maximize efficacy, cost-effectiveness, safety, access for those in need and compliance compared with contemporary evidence-based medicine. Precision medicine emphasizes tailoring diagnostics or therapeutics (prevention or treatment) to subgroups of populations sharing similar characteristics." *"The use of a person's own data to objectively gauge the efficacy, safety, and tolerability of therapeutics, and, subjectively, to tailor health recommendations and/or medical decisions to the individual's preferences, circumstances, and capabilities."*
1.2		State the research question and study design	*'Study design' refers to the specific type of clinical trial design (e.g. parallel arm, randomized cross-over, recall-by-genotype) or observational cohort design (e.g. cross-sectional study, prospective cohort study, case-cohort study, case-control study). If the study design involves time-series assessments this should also be highlighted.*
1.3		Describe if the study relates to prevention, diagnostics, treatment and/or prognostics	
1.4		Describe population or subgroup that is the focus of the current analysis	

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2. Background and Objectives			
2.1		State the study hypothesis describing the specific rationale for the precision medicine approach	
2.2		State the study objective(s) of the precision medicine study as either a) etiological, b) discovery, c) predictive and/or d) confirmatory. State all that apply. See the Explanation and elaborations document for detailed descriptions of the objectives.	*a) Etiological: Characterization of heterogeneity across individual-level data* *b) Discovery: Exploration of associations between a set of clinical features and outcome heterogeneity (e.g. descriptive RCT subgroup analysis or exploratory analysis of risk factors)* *c) Predictive: Development of a specific approach(es) to predict heterogeneity in clinical or treatment-related outcomes for individuals or subgroups* *d) Confirmatory: Reproduction of a previously proposed precision medicine approach*
3. Methods			
3.1		Describe aspects of the study design relevant to precision medicine that are necessary for the design to be adequately understood by the reader.	

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3.2		Provide the rationale for choice of outcome(s).	
3.3		If the dataset is a subset of a larger study, describe how and why the subset(s) of participants used in the analysis was selected.	
3.4		Define any markers used for stratification or prediction of outcomes in individuals or subgroups	*'Markers' in this context could include (and are not limited to) biomarkers, molecular markers and clinical characteristics, as well as societal, economic, geographic, and cultural factors.*
3.5		Provide details of any measures taken to mitigate type 1 and/or type 2 error. Describe *a priori* power calculations and adjustment for multiple-testing, if performed.	
3.6		Describe any approach used for internal and/or external replication and/or validation and whether these analyses were planned, and relevant datasets identified before or after conclusion of primary analyses.	*'Replication' analyses are those that seek to directly reproduce primary analyses. 'Validation' analyses are those that seek to generate results using orthogonal methods to those used in the primary analyses that strengthen its conclusions.*

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3.7		Specify how the sample size for any replication/validation study was determined	
4. Results			
4.1		Specify the number of participants in each analysis and provide baseline characteristics	*If analysis includes comparison of subgroups, baseline characteristics for each subgroup should be provided.*
4.2		Report statistical tests and results for subgroup comparisons.	*Comparisons between subgroups should include appropriate test statistics, which may include tests of interaction and heterogeneity, and in cluster analyses tests of probability for cluster assignment (e.g., relative entropy statistic).*
4.3		If benchmarking against current practice was undertaken, describe these results. State if benchmarking was not performed	*Provide formal comparisons against current practice to assess performance of the precision medicine approach. For example, for prediction models, compare new biomarkers with established prediction variables, formally testing differences in prediction performance. For treatments, compare measures of clinical effectiveness (e.g. number needed to treat) between new and conventional approaches. If such comparisons are not possible, provide an explanation.*

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4.4		Provide results for all attempted validation and/or replication analyses	
5. Discussion			
5.1		General limitations	*Describe how study characteristics or analytical methods may introduce bias, particularly as these pertain to features of the analysis related to precision medicine (e.g., subgroup comparisons)*
5.2		Interpretation: Describe the precision medicine approach that could potentially be applied in clinical practice	