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EASE statement on data sharing

Statement

The European Association of Science Editors (EASE) supports all initiatives on data sharing that are: (i) based on good editorial practice; (ii) take data protection issues into account; and (iii) consider publication ethical codes of conduct. As such, EASE is in agreement with the recently proposed requirement from the International Committee of Medical Journal Editors (ICMJE) that makes sharing of clinical trial data mandatory for manuscript acceptance by its member journals[1].

EASE believes that the transparency of clinical trial conduct and outcomes is paramount to the public's trust in science. Transparency promotes well-informed use of medical interventions, permits verification of research, and helps to avoid duplication (thus reducing research waste). Reuse of shared data enables generation of new knowledge both for current clinical practice and for future research. Thus data sharing has the potential to affect the health both of individuals and the population.

We note that regulators have already taken the initiative for data transparency. The European Medicines Agency made data sharing a legal requirement in October 2014 when it published its final policy on publication of clinical data. This policy applies to clinical reports contained in all initial applications for marketing authorisation submitted on or after 1 January 2015. In March 2016 the Agency issued detailed guidance for pharmaceutical companies on how to comply with this policy[2]. Publication of the first reports to comply with the EMA policy is anticipated in September 2016. Data that will be available include protocols and amendments, sample case report forms, statistical method documentation, clinical study reports, and individual patient data. Thus the path from trial conception to final results will be fully transparent down to the patient level.

Such large-scale sharing of data from clinical trials requires considerable logistic and financial investment and curation. With this in mind, EASE recommends that all stakeholders – researchers, institutions, funders, regulators, journals, and editors – collaborate to develop better access to the results of medical research. EASE advises careful consideration of the following issues.

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A. Non-publication of the results of health research

i. This continues to be an acute problem[3]. It is important that data sharing is linked not only to the publication of results in a journal, but also to:

ii. research funding processes – data management plans should be a part of project proposals as envisaged by the European Commission in Horizon 2020 funding scheme[4].

iii. approval by relevant authorisation bodies (e.g. EMA and FDA).

B. Balance between public benefit and patient privacy

i. Protocols for data preparation, deposition and curation should be developed to maintain a considered balance between public benefit and the privacy of individual trial participants. Any commercial sensitivities regarding making data public should be considered exceptional rather than regular.

C. Storage of datasets.

i. Storage location, security, and access policies and procedures should be defined and enforced, and archiving should be ensured. Among the issues for consideration are use of licenses for datasets, and assignment of persistent digital identifiers (e.g. DOIs as recommend by DataCite)[5,6].

D. Access to data

i. Editors should, in partnership with their publishers, and in consideration of Point B, develop and enforce data access policies in respect of:

ii. reviewer access to data as part of the pre-publication peer review process

iii. public access to data reported in published research articles

iv. reanalysis of data reported in published research articles

v. quality control and reviewing of data[7].

E. Prior/duplicate publication

i. Journal editors should not consider data sharing and data deposition to be prior or duplicate publication.

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