Call for a central portal for clinical study reports

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Clinical study reports (CSRs) are comprehensive, standardized reports on clinical trials that pharmaceutical companies submit to authorities such as the European Medicines Agency (EMA) during drug approval procedures. In Germany, the Institute for Quality and Efficiency in Health Care (IQWiG) has had access to CSRs since 2011 as part of early benefit assessments of new drugs. Staff at the Institute demonstrated

several years ago that CSRs provide by far the most complete evidence on patient-relevant outcomes compared with journal publications or registry entries and are thus the most solid basis for unbiased assessments of drug treatments.

In their paper published in the *Journal of European Continuing Medical Education (CME)*, Natalie McGauran and Beate Wieseler now outline potential uses of CSRs beyond early benefit assessments: The development of clinical practice guidelines, CME materials, and patient information could benefit greatly from a comprehensive, unbiased evidence base.

The IQWiG authors state that for their proposal to work, a central, public, worldwide portal would be needed, because up to now, evidence has been scattered across numerous sources. In the basic structure of such a portal, core information would be immediately available, while, for example, anonymized individual patient data would have to be actively requested. In addition, they suggest expanding the scope of the portal to studies of medical devices and other non-drug interventions.

Since experience shows that voluntary commitments by industry are insufficient, the legislator is called upon to establish such a central portal and to make the submission of CSRs mandatory.

More information: Natalie McGauran et al, Centralised Full Access to Clinical Study Data Can Support Unbiased Guideline Development, Continuing Medical Education, and Patient Information, *Journal of European CME* (2021). DOI: 10.1080/21614083.2021.1989172

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