

Publication

Recommendations for collaborative paediatric research including biobanking in Europe: a Single Hub and Access point for paediatric Rheumatology in Europe (SHARE) initiative

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Innovative research in childhood rheumatic diseases mandates international collaborations. However, researchers struggle with significant regulatory heterogeneity; an enabling European Union (EU)-wide framework is missing. The aims of the study were to systematically review the evidence for best practice and to establish recommendations for collaborative research. The Paediatric Rheumatology European Single Hub and Access point for paediatric Rheumatology in Europe (SHARE) project enabled a scoping review and expert discussion, which then informed the systematic literature review. Published evidence was synthesised; recommendations were drafted. An iterative review process and consultations with Ethics Committees and European experts for ethical and legal aspects of paediatric research refined the recommendations. SHARE experts and patient representatives vetted the proposed recommendations at a consensus meeting using Nominal Group Technique. Agreement of 80% was mandatory for inclusion. The systematic literature review returned 1319 records. A total of 223 full-text publications plus 22 international normative documents were reviewed; 85 publications and 16 normative documents were included. A total of 21 recommendations were established including general principles (1-3), ethics (4-7), paediatric principles (8 and 9), consent to paediatric research (10-14), paediatric databank and biobank (15 and 16), sharing of data and samples (17-19), and commercialisation and third parties (20 and 21). The refined recommendations resulted in an agreement of >80% for all recommendations. The SHARE initiative established the first recommendations for Paediatric Rheumatology collaborative research across borders in Europe. These provide strong support for an urgently needed European framework and evidence-based guidance for its implementation. Such changes will promote research in children with rheumatic diseases.

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