



Invitation to sites to document Paediatric and adolescent mpox cases for VERDI “Mpox paediatric and adolescent clinical study”

We would like to invite you to take part in a study of mpox in children and adolescents globally. The study aims to collect harmonised data on monkeypox virus infection in these groups to enable epidemiological analysis of the combined dataset.

The state of knowledge regarding the epidemiology, clinical presentation and outcomes of mpox disease in children and adolescents is limited. There is currently a need for a harmonized EU paediatric clinical protocol for standardized collection and analysis of data on monkeypox virus infection in this group.

WHO WE ARE

This study is a **Joint EU Clinical Research Initiative** which is part of the VERDI (SARS-coV2 variants Evaluation in pRegnancy and paeDIiatrics cohorts) project, in collaboration with VACCELERATE. VERDI is coordinated by the University of Padova, and this study is sponsored by Fondazione Penta Onlus, both based in Padova, Italy.

We are establishing a **standard observational mpox** data collection system (for collection of data on both retro- and prospective cases) with the initial goal of describing the presentation, clinical course, and outcomes of children and adolescents (0-17 years old at mpox diagnosis) with laboratory-confirmed MPXV infection.

OVERVIEW OF STUDY PROCEDURES

- **Phase 1:** with collection of anonymised data from routine care on children and adolescents with laboratory-confirmed mpox virus infection. Requirement for ethics approvals dependant on local regulation. Starts in February 2023.
- **Phase 2:** establishment of an enhanced observational cohort of children and adolescents with confirmed mpox virus infection. This will be a consented study collecting detailed pseudonymised data, including longer term follow-up through data linkage and / or direct patient contact. A site feasibility assessment will be performed prior to joining this phase of the study and local ethics approval will be required. The decision about whether to carry phase 2 will be based on the ongoing case numbers and the existence of other surveillance systems/studies.
- **Phase 3:** potential sub-studies may be added for sites in phase 2. More information to be shared in due course.

WHO CAN PARTICIPATE

All sites:

- including university, non-academic, tertiary care and community hospitals,
- with or without prior experience in carrying out research projects,
- who are or will be taking care of children or adolescents (as inpatients or outpatients) with confirmed mpox

are encouraged to express their interest in Phase 1 and / or Phase 2 of the study by completing this survey: <https://forms.office.com/e/q1kdsUEbT5>

If you have already received this letter, please only answer the survey once for each site.



If you have not seen any cases of mpox at your site but do have cases in any possible future waves, we would be grateful if you could contact us and join the registry at that time. We will be collecting patient data until June 2024.

Please note, researchers contributing to the study will be included on study publications.

The Sponsor, Fondazione Penta Onlus, will contact sites who express an interest in participating in the registry to check regulatory approval requirements and compliance after which access will be given to the online platform for **phase 1**.

Please do not hesitate to contact Giorgia Dalla Valle, the clinical project manager (giorgia.dallavalle@pentafoundation.org) for any further information.

Yours sincerely,

Laura Mangiarini
Chief Program Officer
Fondazione Penta Onlus