

# Paediatric Clinical Trial Site Mapping Survey

This survey was designed by the World Health Organization (WHO) Global Accelerator for Paediatric Formulations (GAP-f) Network, with the goal of mapping clinical research sites with capacity to participate in paediatric clinical trials to inform approval and optimal use of paediatric medicines.

Upon completion of the survey, summarized information may be included in a publicly available global mapping of paediatric clinical trial sites. This mapping is intended to facilitate collaboration among research sites, study sponsors, and funders.

The survey will also help identify areas where additional support may be required to prepare sites for future paediatric studies. Information related to capacity-strengthening needs will remain confidential and will be used solely by GAP-f to inform future initiatives aimed at strengthening the clinical trial ecosystem.

The survey should be completed by the individual most familiar with the research site, such as the Principal Investigator or Lead Clinical Investigator. One survey should be completed for each research site or unit.

**Privacy Statement:** WHO processes personal data in accordance with its data protection framework, comprising of the United Nations Personal Data Protection and Privacy Principles and the WHO Personal Data Protection Policy.

There are 48 questions in this survey.

## Information about person completing the form

Name (First, Last) \*

Please write your answer here:

Job title \*

Please write your answer here:

E-mail address \*

Please check the format of your answer.

Please write your answer here:

## Research site information

Please, add this information related to your **research site** \*

Please write your answer(s) here:

Institution name

Address

City

Country

Institution website if applicable

## Qualification and experience

Has your research site participated in paediatric clinical trials in the past 5 years? \*

Choose one of the following answers

Please choose **only one** of the following:

Yes

No

If no, why? (mark all that apply)

Only answer this question if the following conditions are met:

Answer was 'No' at question ' [Q001]' (Has your research site participated in paediatric clinical trials in the past 5 years?)

Select all that apply

Please choose **all** that apply:

- Limited funding
- Limited capacity
- Lack of leadership (investigator)
- Have not been asked
- Limited access to pediatric patient population
- Institutional barriers to participation
- Unaware of clinical trials seeking patients

Other:

Do the Principal Investigator(s) (PI) and site staff have a documented International Council for Harmonisation's Good Clinical Practice (ICH-GCP) training certificate that is current (within last 3 years)?

\*

Only answer this question if the following conditions are met:

Answer was 'Yes' at question ' [Q001]' (Has your research site participated in paediatric clinical trials in the past 5 years?)

Choose one of the following answers

Please choose **only one** of the following:

Yes

No

What diseases or therapeutic areas has your site conducted research on in children in the past 5 years? (Mark all that apply)

\*

Only answer this question if the following conditions are met:

Answer was 'Yes' at question ' [Q001]' (Has your research site participated in paediatric clinical trials in the past 5 years?)

Select all that apply

Please choose **all** that apply:

- HIV
- Tuberculosis
- Hepatitis
- Viral respiratory diseases (RSV, influenza, COVID)
- Bacterial or fungal infections
- Malaria
- Dengue
- Neglected Tropical Diseases (i.e., Leishmaniasis, schistosomiasis, Human African Trypanosomiasis (HAT), onchocerciasis, scabies, helminthiasis)
- Childhood cancer
- Sickle cell disease
- Epilepsy
- Other:

What types of paediatric studies does the site have experience with in the past 5 years? (Mark all that apply)

\*

Only answer this question if the following conditions are met:

Answer was 'Yes' at question ' [Q001]' (Has your research site participated in paediatric clinical trials in the past 5 years?)

Select all that apply

Please choose **all** that apply:

- Diagnostics
- Prevention (vaccines, monoclonal antibodies)
- Treatment (therapeutics, devices)
- None of the above

Indicate which phase(s) of research your site has experience with a **diagnostic** study (mark all that apply)

Only answer this question if the following conditions are met:

Answer was 'Diagnostics' at question ' [Q004]' (What types of paediatric studies does the site have experience with in the past 5 years? (Mark all that apply) )

Select all that apply

Please choose **all** that apply:

- Phase 1 trial
- Phase 1/2 trial
- Phase 2 trials
- Phase 3 trials
- Phase 4 trials
- Pharmacokinetic (PK) studies
- Observational studies (no investigational drugs/non-interventional)
- Paediatric operational/implementation science studies
- None
- Other:

Indicate which phase(s) of research your site has experience with a **prevention (vaccines, mAbs)** study (mark all that apply)

Only answer this question if the following conditions are met:

Answer was 'Prevention (vaccines, monoclonal antibodies)' at question ' [Q004]' (What types of paediatric studies does the site have experience with in the past 5 years? (Mark all that apply) )

Select all that apply

Please choose **all** that apply:

- Phase 1 trial
- Phase 1/2 trial
- Phase 2 trials
- Phase 3 trials
- Phase 4 trials
- Pharmacokinetic (PK) studies
- Observational studies (no investigational drugs/non-interventional)
- Paediatric operational/implementation science studies
- None
- Other:

Indicate which phase(s) of research your site has experience with a **treatment (therapeutics, devices)** study (mark all that apply)

Only answer this question if the following conditions are met:

Answer was 'Treatment (therapeutics, devices)' at question ' [Q004]' (What types of paediatric studies does the site have experience with in the past 5 years? (Mark all that apply) )

Select all that apply

Please choose **all** that apply:

- Phase 1 trial
- Phase 1/2 trial
- Phase 2 trials
- Phase 3 trials
- Phase 4 trials
- Pharmacokinetic (PK) studies
- Observational studies (no investigational drugs/non-interventional)
- Paediatric operational/implementation science studies
- None
- Other:

## If your site has conducted PK studies, has your site conducted **intensive PK studies**?

Only answer this question if the following conditions are met:

Answer was 'Treatment (therapeutics, devices)' or 'Prevention (vaccines, monoclonal antibodies)' or 'Diagnostics' at question ' [Q004]' (What types of paediatric studies does the site have experience with in the past 5 years? (Mark all that apply) )

Choose one of the following answers

Please choose **only one** of the following:

- Yes
- No
- Not applicable (site has not conducted PK studies)

## In what age groups has your site conducted intensive PK studies?

Only answer this question if the following conditions are met:

Answer was 'Treatment (therapeutics, devices)' or 'Prevention (vaccines, monoclonal antibodies)' or 'Diagnostics' at question ' [Q004]' (What types of paediatric studies does the site have experience with in the past 5 years? (Mark all that apply) )

Select all that apply

Please choose **all** that apply:

- Newborn (less than 28 days)
- 28 days to less than 2 years
- 2-5 years of age
- 2-12 years of age
- 13-17 years of age
- Not applicable (site has not conducted intensive PK studies)

Has the site participated in an academic paediatric research network within the past 5 years?

Only answer this question if the following conditions are met:

Answer was 'Yes' at question ' [Q001]' (Has your research site participated in paediatric clinical trials in the past 5 years?)

Choose one of the following answers

Please choose **only one** of the following:

- Yes
- No
- Do not know

If yes, specify network name, and indicate "current" or "past" for status of inclusion in the network.

Only answer this question if the following conditions are met:

Answer was 'Yes' at question ' [Q0010]' (Has the site participated in an academic paediatric research network within the past 5 years? )

Please write your answer(s) here:

Network 1

Network 2

Network 3

Network 4

Network 5

## Approximately how many paediatric trials has the site participated in over the past 5 years? \*

Only answer this question if the following conditions are met:

Answer was 'Do not know' or 'No' or 'Yes' at question ' [Q0010]' (Has the site participated in an academic paediatric research network within the past 5 years? )

Please write your answer here:

Across all research conducted at your site, which age group(s) have you previously enrolled in research? (Mark all that apply)

\*

Only answer this question if the following conditions are met:

Answer was 'Yes' at question ' [Q001]' (Has your research site participated in paediatric clinical trials in the past 5 years?)

Select all that apply

Please choose **all** that apply:

- Newborn (less than 28 days)
- 28 days and less than 2 years
- 2-5 years of age
- 6-12 years of age
- 13-17 years of age

Have you received public funding (e.g., national governments) for paediatric research over the past five years?

Only answer this question if the following conditions are met:

Answer was 'Yes' at question ' [Q001]' (Has your research site participated in paediatric clinical trials in the past 5 years?)

Choose one of the following answers

Please choose **only one** of the following:

- Yes
- No
- Don't know

If yes, indicate countries or regional bodies from which funding was received

Only answer this question if the following conditions are met:

Answer was 'Yes' at question ' [Q0014]' (Have you received public funding (e.g., national governments) for paediatric research over the past five years? )

Please write your answer here:

Have you received private funding for paediatric research over the past five years (e.g., pharmaceutical, foundations)?

Only answer this question if the following conditions are met:

Answer was 'Yes' at question ' [Q001]' (Has your research site participated in paediatric clinical trials in the past 5 years?)

Choose one of the following answers

Please choose **only one** of the following:

- Yes
- No
- Do not know

If you have received **private funding** for paediatric research in the past 5 years, please mark all that apply:

Only answer this question if the following conditions are met:

Answer was 'Yes' at question ' [Q0015]' (Have you received private funding for paediatric research over the past five years (e.g., pharmaceutical, foundations)? )

Select all that apply

Please choose **all** that apply:

- Pharmaceutical companies
- Foundations
- Non-governmental organizations (NGOs)
- Other:

Has your site participated in a paediatric clinical trial that required regulatory oversight of a **WHO Listed Authority (WLA)** or a **national regulatory authority (NRA)** operating at maturity level 3 or 4? \*

Only answer this question if the following conditions are met:

Answer was 'Yes' at question ' [Q001]' (Has your research site participated in paediatric clinical trials in the past 5 years?)

Choose one of the following answers

Please choose **only one** of the following:

- Yes
- No
- Do not know

If yes, which type of regulatory authority? \*

Only answer this question if the following conditions are met:

Answer was 'Yes' at question ' [Q0017]' (Has your site participated in a paediatric clinical trial that required regulatory oversight of a WHO Listed Authority (WLA) or a national regulatory authority (NRA) operating at maturity level 3 or 4?)

Select all that apply

Please choose **all** that apply:

- WHO Listed Authority
- National Regulatory Authority ML3
- National Regulatory Authority ML4
- I do not know

## Facilities and resources

Does the research site have a dedicated clinical trial unit? \*

Only answer this question if the following conditions are met:

Answer was 'Limited funding' or 'Limited capacity' or 'Lack of leadership (investigator)' or 'Have not been asked' or 'Limited access to pediatric patient population' or 'Institutional barriers to participation' or 'Unaware of clinical trials seeking patients' at question ' [Q001a]' (If no, why? (mark all that apply))

Choose one of the following answers

Please choose **only one** of the following:

- Yes
- No
- Do not know

Is the research site or clinical research unit linked to, or within, a health facility that serves children? \*

Only answer this question if the following conditions are met:

Answer was 'Do not know' or 'No' or 'Yes' at question ' [Q0019]' (Does the research site have a dedicated clinical trial unit?)

Choose one of the following answers

Please choose **only one** of the following:

- Yes
- No

## Which type of health facility is the site within?

Only answer this question if the following conditions are met:

Answer was 'Yes' at question ' [Q0020]' (Is the research site or clinical research unit linked to, or within, a health facility that serves children?)

Choose one of the following answers

Please choose **only one** of the following:

Private clinic

Public clinic

Private hospital

Public hospital

Other

## Which departments does the health facility have? (mark all that apply)

Only answer this question if the following conditions are met:

Answer was 'Yes' at question ' [Q0020]' (Is the research site or clinical research unit linked to, or within, a health facility that serves children?)

Select all that apply

Please choose **all** that apply:

Paediatric

Neonatal

Paediatric Intensive Care Unit (PICU)

Neonatal Intensive Care Unit (NICU)

Other:

## What diseases or therapeutic areas does the facility diagnose or treat in children? (Mark all that apply)

Only answer this question if the following conditions are met:

Answer was 'Yes' at question ' [Q0020]' (Is the research site or clinical research unit linked to, or within, a health facility that serves children?)

Select all that apply

Please choose **all** that apply:

- HIV
- Tuberculosis
- Hepatitis
- Viral respiratory diseases (RSV, influenza, COVID)
- Bacterial or fungal infections
- Malaria
- Dengue
- Neglected Tropical Diseases (i.e., Leishmaniasis, schistosomiasis, Human African Trypanosomiasis (HAT), onchocerciasis, scabies, helminthiasis)
- Childhood cancer
- Sickle cell disease
- Epilepsy
- Other:

Which age group(s) could you enroll at your site? Consider the available patient population at the health facility or in the community. (Mark all that apply)

Only answer this question if the following conditions are met:

Answer was 'Yes' at question ' [Q0020]' (Is the research site or clinical research unit linked to, or within, a health facility that serves children?)

Select all that apply

Please choose **all** that apply:

- Newborn (less 28 days)
- 28 days and less than 2 years
- 2 - 5 years of age
- 6 - 12 years of age
- 13 - 17 years of age

Does the site have a dedicated clinical pharmacy for storage, preparation, and dispensing of study drugs? \*

Only answer this question if the following conditions are met:

Answer was 'No' or 'Yes' at question ' [Q0020]' (Is the research site or clinical research unit linked to, or within, a health facility that serves children?)

Choose one of the following answers

Please choose **only one** of the following:

- Yes
- No
- Do not know

## Does the site have access to a clinical laboratory? \*

Choose one of the following answers

Please choose **only one** of the following:

- Yes
- No
- Do not know

## What type of laboratory? \*

Only answer this question if the following conditions are met:

Answer was 'Yes' at question ' [Q0026]' ( Does the site have access to a clinical laboratory?)

Select all that apply

Please choose **all** that apply:

- Central lab
- Local/hospital lab
- Reference lab
- Academic/University lab
- Government lab
- Industry/pharma lab

Does the laboratory have capacity to process and store clinical samples at -70C/-80F? \*

Only answer this question if the following conditions are met:

Answer was 'Yes' at question ' [Q0026]' ( Does the site have access to a clinical laboratory?)

Choose one of the following answers

Please choose **only one** of the following:

- Yes
- No
- I do not know

Does the site have staff trained in collection of study data using electronic data capture (EDC) systems (e.g., REDCap, OpenClinica)? \*

Only answer this question if the following conditions are met:

Answer was 'Do not know' or 'No' or 'Yes' at question ' [Q0026]' ( Does the site have access to a clinical laboratory?)

Choose one of the following answers

Please choose **only one** of the following:

- Yes
- No
- I do not know

Does the site have access to paediatric electronic medical records (EMR)? \*

Choose one of the following answers

Please choose **only one** of the following:

- Yes
- No
- I do not know

Does the site use standard operating procedures (SOPs) and/or guidelines for conducting research in children that are adapted to clinical trial protocol-specific requirements, as applicable? (For example, biological specimen collection guidelines relevant to minimum and maximum blood volumes, strategies for community and family engagement, guidelines for administering informed consent and assent to children and families.) \*

Choose one of the following answers

Please choose **only one** of the following:

- Yes
- No
- Do not know

## Specify the type of paediatric SOPs/guidelines available at the site: \*

Only answer this question if the following conditions are met:

Answer was 'Yes' at question ' [Q0031]' (Does the site use standard operating procedures (SOPs) and/or guidelines for conducting research in children that are adapted to clinical trial protocol-specific requirements, as applicable? (For example, biological specimen collection guidelines relevant to minimum and maximum blood volumes, strategies for community and family engagement, guidelines for administering informed consent and assent to children and families.))

Select all that apply

Please choose **all** that apply:

- SOPs for clinical and anthropometric assessments in children
- SOPs for paediatric neurological assessments
- SOPs for biospecimen collection
- Plan for community, family, and patient engagement in paediatric research
- Procedures for patient recruitment, follow-up, and retention specific to children and families
- Informed consent/ assent for children and families
- Other:

## Clinical research capacity

Please rank the following areas of clinical research capacity. If limited or basic capacity is checked, describe the capacity strengthening needs at the site in the open text section below. Think about the factors or resources needed that would allow your site to successfully conduct a clinical trial of paediatric medicines.

### Data collection for clinical trials \*

Choose one of the following answers

Please choose **only one** of the following:

- Well established
- Limited capacity
- Basic capacity
- Not applicable to site
- Do not know

### Regulatory/Ethics Committee documentation preparation and submission \*

Choose one of the following answers

Please choose **only one** of the following:

- Well established
- Limited capacity
- Basic capacity
- Not applicable to site
- Do not know

## Biological specimen collection and transport \*

Choose one of the following answers

Please choose **only one** of the following:

- Well established
- Limited capacity
- Basic capacity
- Not applicable to site
- Do not know

## Laboratory processing, diagnostic testing, & storage \*

Choose one of the following answers

Please choose **only one** of the following:

- Well established
- Limited capacity
- Basic capacity
- Not applicable to site
- Do not know

## Clinical pharmacy for storage, preparation and dispense study drugs \*

Choose one of the following answers

Please choose **only one** of the following:

- Well established
- Limited capacity
- Basic capacity
- Not applicable to site
- Do not know

## Clinical research staff recruitment and training \*

Choose one of the following answers

Please choose **only one** of the following:

- Well established
- Limited capacity
- Basic capacity
- Not applicable to site
- Do not know

## Budgeting & financial oversight of research funding \*

Choose one of the following answers

Please choose **only one** of the following:

- Well established
- Limited capacity
- Basic capacity
- Not applicable to site
- Do not know

## Public and patient engagement/ involvement \*

Choose one of the following answers

Please choose **only one** of the following:

- Well established
- Limited capacity
- Basic capacity
- Not applicable to site
- Do not know

If limited or basic capacity, describe capacity strengthening needs for the respective area (otherwise, leave the field empty)

Please write your answer(s) here:

Data collection for clinical trials

Regulatory/Ethics Committee documentation preparation and submission

Biological specimen collection and transport

Laboratory processing, diagnostic testing, & storage

Clinical pharmacy for storage, preparation and dispense study drugs

Clinical research staff recruitment and training

Budgeting & financial oversight of research funding

Public and patient engagement/ involvement

## Additional information

Provide any other information about your site related to paediatric clinical trial experience and capacity not included in the sections above.

Please write your answer here:

Submit your survey.

Thank you for completing this survey.