

Service Request Form

Submitted by (Name)	
Organisation	Organisation: Address: Type of organisation: <input type="checkbox"/> Academia <input type="checkbox"/> Industry <input type="checkbox"/> Patient organisation <input type="checkbox"/> Other, please specify _____
Date of request submission	

Section A – **Non-confidential** summary

Non-confidential summary	
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Note: the above non-confidential summary will be used for review, control and potential public communications purposes. Should you wish to prevent this summary being used for public communications purposes, please tick below.

I do not want this summary to be used for public communications purposes.

The form requires the following information: name of the user, user institution, contacts, service requested, and a short description of the context of the request (a maximum of 4 lines).

Section B – Scientific rationale and paediatric use - **Confidential**

Required fields are marked with an asterisk *.

All entries in this section of the form are confidential to EPTRI.

Submitted by (Name)*	
Organisation*	<p>Organisation: Address:</p> <p>Type of organisation:</p> <p><input type="checkbox"/> Academia</p> <p><input type="checkbox"/> Industry</p> <p><input type="checkbox"/> Patient organisation</p> <p><input type="checkbox"/> Other, please specify _____</p>
Service specification*	<p>Centralised services</p> <p><input type="checkbox"/> Support in scouting and application to funding opportunities</p> <p><input type="checkbox"/> Research project management</p> <p><input type="checkbox"/> Advice on the design and requirements of not clinical specific studies/experiments</p> <p><input type="checkbox"/> Advice on translation to clinical phases</p> <p>Common services</p> <p><input type="checkbox"/> Ethical, legal and societal issues (ELSI) service</p> <p><input type="checkbox"/> Paediatric data interoperability service</p> <p>Integrated services - Paediatric Medicines Discovery</p> <p><input type="checkbox"/> In vitro screening of novel drugs using paediatric cellular targets</p> <p><input type="checkbox"/> In vitro pre-clinical studies (effect, efficacy, biomarkers, etc.) in paediatric cell models</p> <p><input type="checkbox"/> Access to the neonatal and juvenile animal models to screen novel drug for a paediatric specific target</p> <p><input type="checkbox"/> Access to the neonatal and juvenile animal models to perform preclinical studies</p> <p><input type="checkbox"/> In silico screening of novel drugs for specific paediatric targets</p> <p><input type="checkbox"/> In silico prediction of ADME properties & toxicity for new molecular entity of paediatrics interest</p> <p><input type="checkbox"/> Scientific advice on specific research questions</p>

	<p>Integrated services – Paediatric Biomarkers and Biosamples</p> <ul style="list-style-type: none"> <input type="checkbox"/> Access to/deposit of annotated paediatric biological samples <input type="checkbox"/> RNA transcripts and DNA variants Biomarker identification and characterisation in paediatric samples. <input type="checkbox"/> Protein Biomarker identification and characterisation in paediatric samples. <input type="checkbox"/> Metabolite candidate Biomarker identification and characterisation in paediatric samples. <input type="checkbox"/> Bioinformatics for the analysis of the data generated by omics platform. <input type="checkbox"/> Verification in paediatric samples of the presence and levels of biomarkers (metabolites, proteins, RNA transcripts, DNA variants) that had been previously identified in adult samples or other candidate biomarkers <input type="checkbox"/> Scientific advice on specific research questions <p>Integrated services – Developmental Pharmacology</p> <ul style="list-style-type: none"> <input type="checkbox"/> Microdosing to establish the “in vivo” PK profile of the new drug <input type="checkbox"/> In vitro models to study ontogeny of drug disposition <input type="checkbox"/> Placental studies <input type="checkbox"/> In vivo toxicity juvenile animal studies <input type="checkbox"/> Paediatric ADME and modelling and simulation <input type="checkbox"/> Sensitive analytical methods adapted to paediatrics <p>Integrated services – Paediatric Medicines Formulations</p> <ul style="list-style-type: none"> <input type="checkbox"/> Pre-formulation advice and Pre-formulation studies <input type="checkbox"/> Formulation of drug for paediatric use for enteral routes of administration <input type="checkbox"/> Formulation of drug for paediatric use for non-enteral routes of administration <input type="checkbox"/> Assessment of drug delivery systems for enteral and non-enteral routes of administration <input type="checkbox"/> in vitro palatability assessment <input type="checkbox"/> in vivo palatability assessment
Clear description of the service*	

List of contacts with user (To be filled in by EPTRI)

Description of the context in which the service is required (research project/product development/other)	<input type="checkbox"/> research project <input type="checkbox"/> product development <input type="checkbox"/> other (please specify)_____
Scientific rationale and background	<i>Please describe the scientific novelty, international scientific visibility, expected societal impact, and the relevant paediatric research need</i>
Possible bottlenecks	<i>Do you anticipate difficulties or problems during development? Please, describe</i>
Financing	Expected source and type of (co)funding for this service request: Current funding status:
Proposed duration of service	Start date: End date:
ID	To be filled in by EPTRI
Service Manager	To be filled in by EPTRI
Email address of Service Manager	To be filled in by EPTRI
Other relevant information and references	

EP TRI contact	User contact	Date, time	File name \ Links