

Thematic Research Platform on Paediatric Medicines Formulations

Elisa Alessandrini – University College London

EPTRI Stakeholders Roundtable – 09th Jul 2020



Platform Overview

- Dedicated to formulation activities to create suitable paediatric medicines in a timely and efficient way
- Organisation of expertise into services' packages
- Matching with experts able to deliver specialised activities

Facilitate and accelerate development of age-appropriate formulations for children





Focus of the TRP

Pre-formulation capabilities



Formulation development



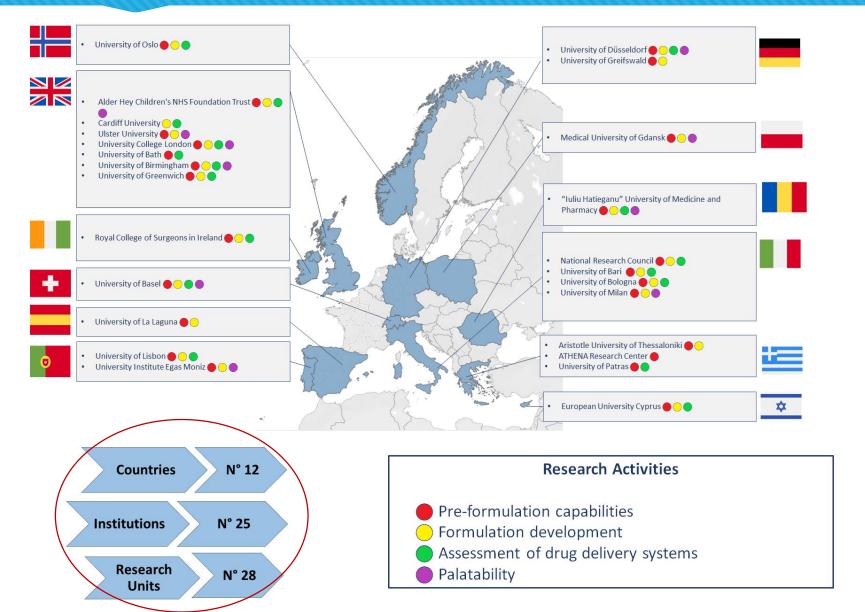
Assessment of drug delivery systems

Palatability





Distribution of Research Institutions and Activities



Research Activities

Pre-formulation capabilities

- Technologies for drug substance characterization
- Solubility enhancement
- Accelerated stability

Formulation development

- Preparation of enteral dosage forms (e.g. microparticulates, orosoluble or orodispersable molded tablets)
- Preparation of non-enteral dosage forms (e.g. nasal, pulmonary, rectal)

Assessment of drug delivery systems

- Modified release profile
- Delivery systems for biologics

Palatability

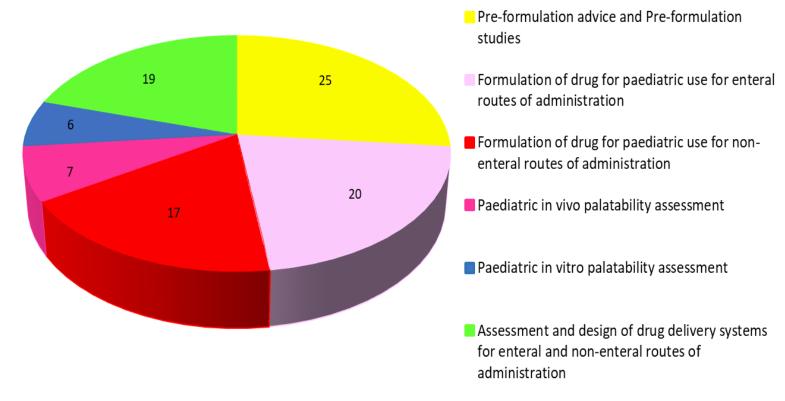
- Equipment for in vitro palatability assessments
- Animal-based and human-based essays
- Palatability assessment with human panels





Services provided

- Services are distributed among the Research Units
- All the services are related to the four research activities







TRP Operational Workflow

User submits a detailed description of the requested service/s



Central Management Office (CMO) will provide a Single Access Point to the available services



The users' requests will be processed by CMO to collect all the information needed for the evaluation



The Access Management Committee, including TRPs Leaders, will evaluate the **Excellence**, **Relevance and In-scope** with EPTRI, the relation of each request to the service



Identification of the possible RUs/providers

- Services proposed will be gradually available based on service providers' readiness
- A dedicated agreement will be set up between the user and CMO to establish criteria for service provision





Conclusions

- Participating research units offering their expertise and activities in paediatric formulation
- All services to be provided fall under four research activities
- Good geographical distribution of the potential service providers
- Services will be delivered through the EPTRI platform to facilitate and enable timely and efficient formulation of suitable paediatric medicines





Thank you



