

ePTRI

EUROPEAN PAEDIATRIC TRANSLATIONAL RESEARCH INFRASTRUCTURE

Thematic Research Platform on Paediatric Formulations

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Focus of This Thematic Platform

Facilitate and accelerate development of age-appropriate formulations for children

Development of new
paediatric formulations



Formulation assessment,
quality control, and
regulation input

Improvement of existing
paediatric formulations

Our Aims

- To **join forces** to tackle the challenges in developing paediatric formulations
- To **bring together** major European research groups/networks (eg European Pediatric Formulation Initiative - EuPFI; European Network on Understanding Gastrointestinal Absorption-related Processes - UNGAP)
- To **establish the future model** of paediatric formulation/*device* thematic research platform

in order to

**expedite the adoption of innovative platforms/technologies
for better and safer dosage forms for children**



Today

- To outline **partner institutions** with expertise in paediatric medicine formulations
 - To delineate **resources (technologies and facilities)** that partner institutions can put at EPTRI's disposal
 - To delineate **service areas** covered by the new platform
- *Results of WP3 survey were used for this purpose*



User needs

Principal **needs** of those working in paediatric medicine development according to WP3 survey:

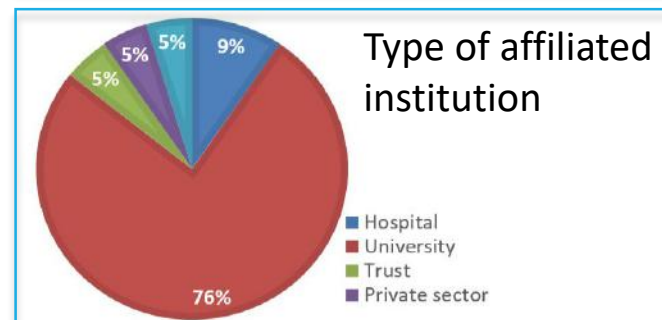
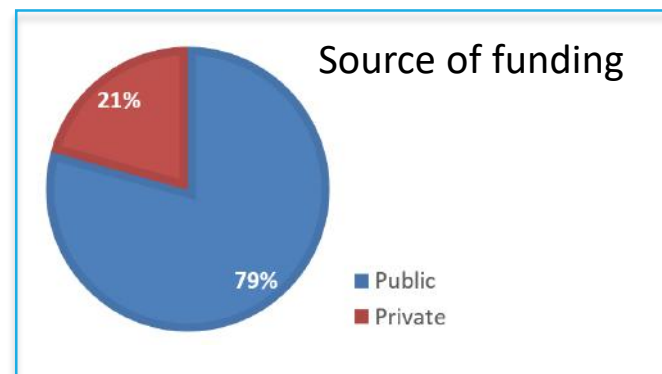
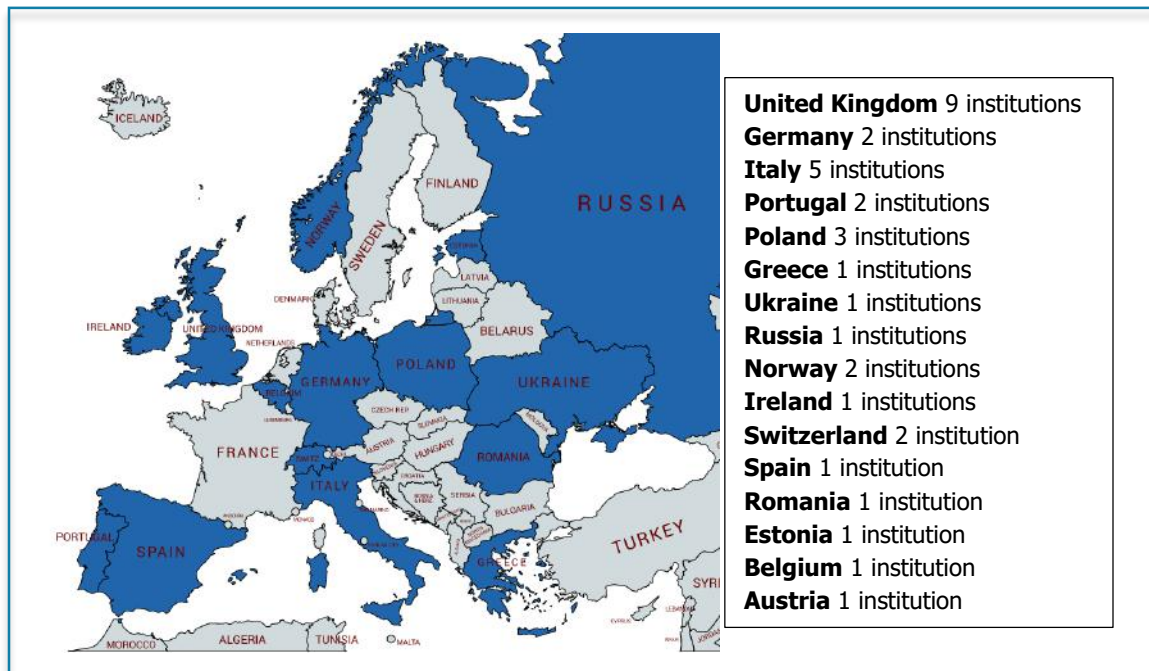
- Specialized services to better enable the development of age-appropriate formulations e.g. patient centric and regulatory fit for purpose dosage forms, acceptability assessments (vitro, vivo)
- Appropriate delivery systems and delivery devices for new active pharmaceutical ingredient (API)
- Prospecting for improved formulation of existing API (*reformulating, repurposing*)



Partner Institutions

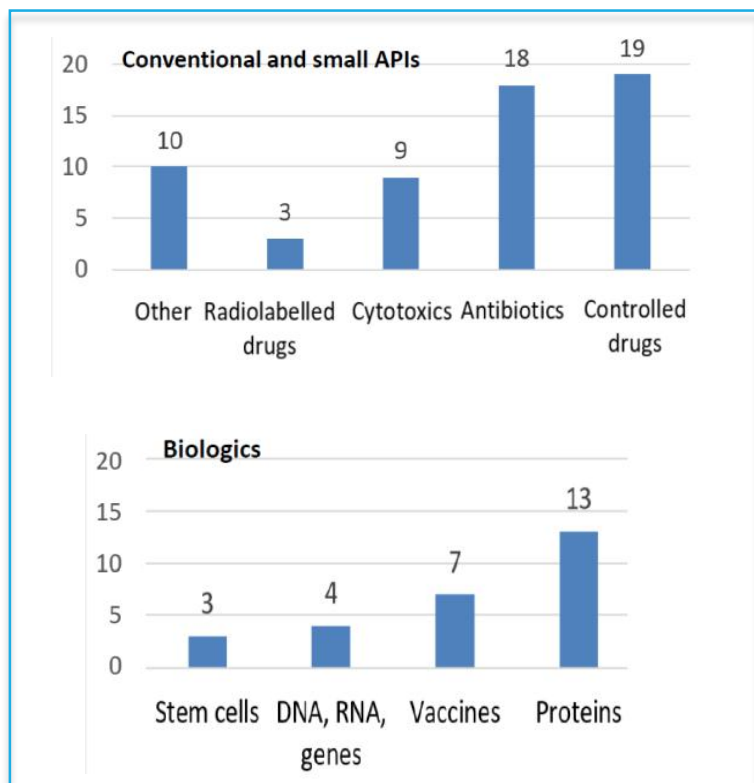
From WP3 survey:

- “*paediatric medicines formulations*” was the major area of interest for 33
- evenly distributed across Europe



Facilities

- Partner institutions have **facilities equipped with technologies** described above
- They also have **facilities adequate to formulate several types of drugs and formulations**



Types of oral formulations

Tablets
Capsules
Orally disintegrating tablets
Orally dissolving films
Chewable tablets
Effervescent tablets
Granules
Minitablets
Microtablets
Solutions
Suspensions
Emulsions
Gels
Pastes

Other formulations

Skin
Eye
Ear
Nail
Rectal
Vaginal
Pulmonary
Nasal
Intravenous
Intramuscular
Subcutaneous liquid
Subcutaneous microneedle patches
Subcutaneous implants

Service Areas in Paediatric Formulations

Available expertise that partner institutions can offer, was streamlined into service areas:

Advisory services for paediatric formulation

Pre-formulation assessments

**Conventional dosage form formulation
(oral & non-oral route)**

**Patient experience (taste masking) technology
and assessments**

Formulating delivery systems for biologics

**Formulating drugs in need of modified release
profile**

**Performance assessment of drug delivery
systems**

Process development and validation

**Product presentation
(administration device compatibility, packaging)**



Formulation related advisory services

EPTRI platform can provide various advisory services:

- **Formulation feasibility** to ensure clients have a realistic expectation of the services to be provided, including timelines, costs, etc
- **Appropriate drug delivery**, to advice clients on various formulation options
- **Innovation**, to advice clients on the latest technologies and formulation strategies applicable to paediatric medicines
- **Regulatory advice**, provide clients with advices towards the quality section of paediatric investigational plan (PIP), and other services in support of authorising



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Performance assessment for drug delivery systems

EPTRI platform can make available several tests required for regulatory approvals:

- **VITRO**

- **Lab-based tests:** Pharmacopoeial tests

e.g. weight uniformity, hardness and friability tests, drug release studies, drug stability tests...



- **VIVO**

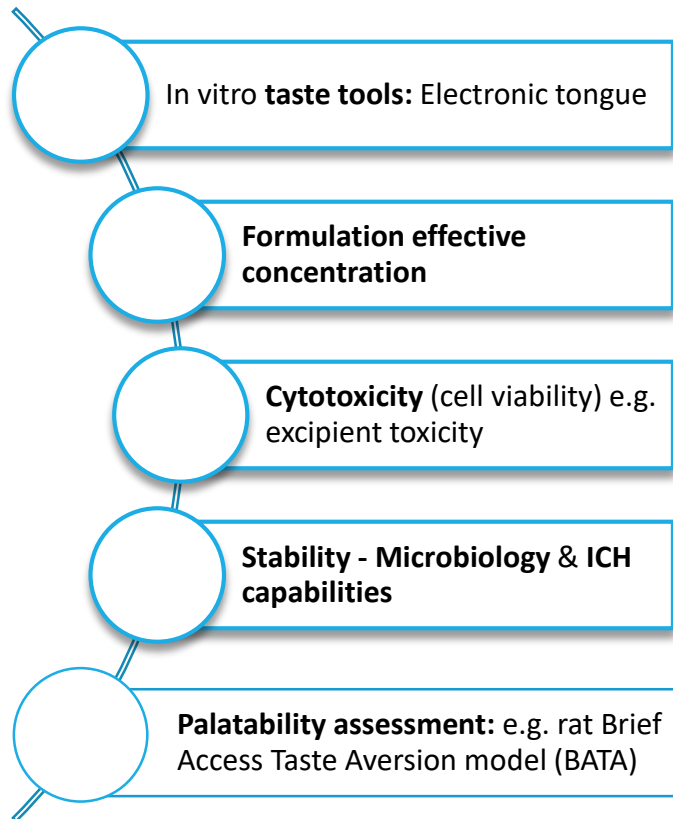
- **Human-based studies:**

eg acceptability, organoleptic tests to assess dosage form acceptability

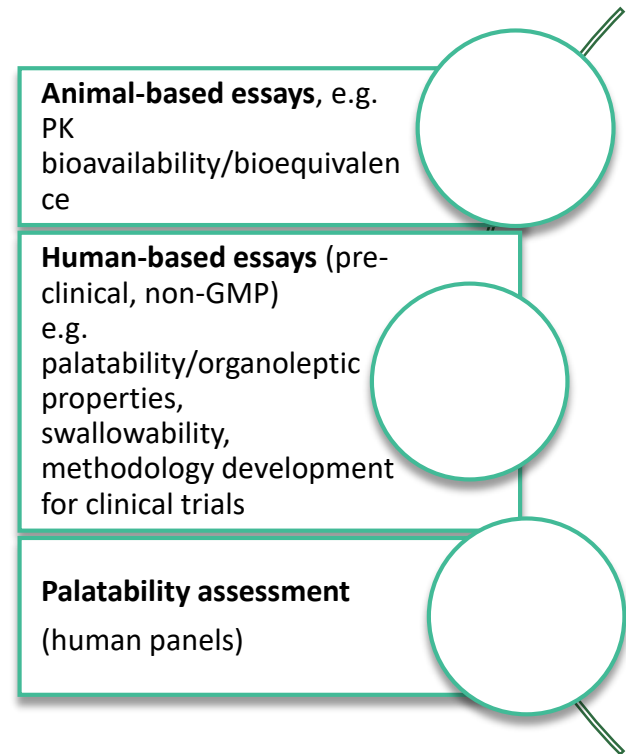


Technologies offered by partner institutions

In vitro drug product characterisation



In vivo drug product characterisation



Technologies offered by partner institutions

Pre-formulation capabilities



Drug substance characterisation

Solubility, enhancement & accelerated stability

Excipient safety (e.g. STEP database, tox assays)

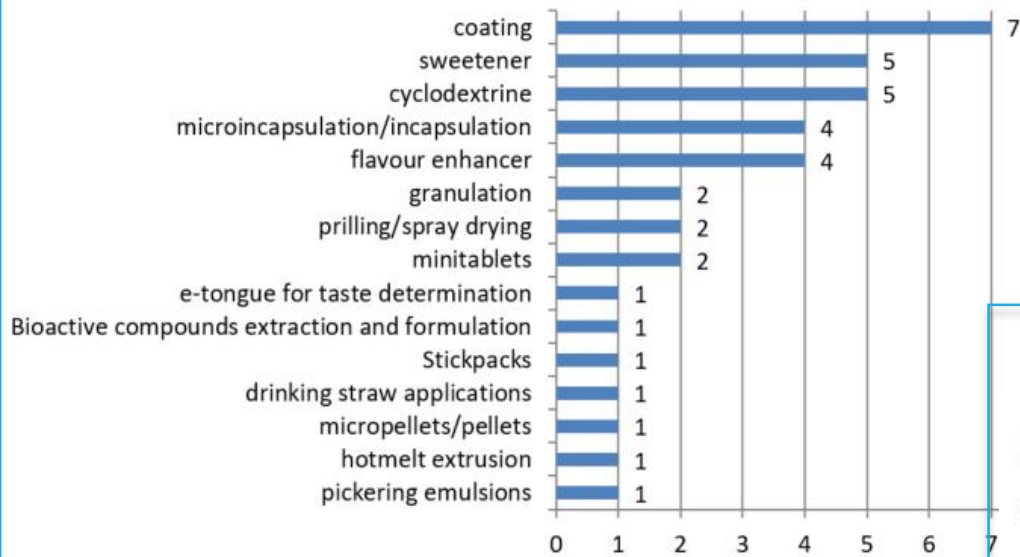
Permeability studies

Drug excipients and drug components compatibility

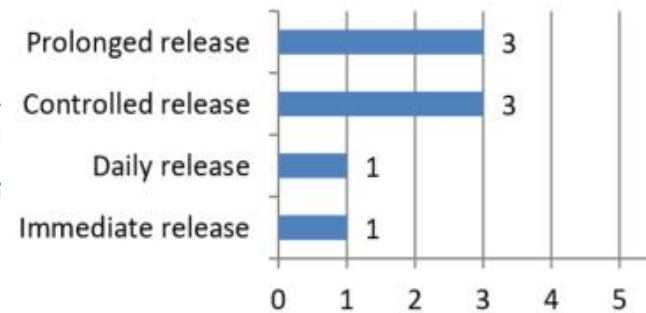
BCS classification

Technologies offered by partner institutions

Taste-masking technologies:

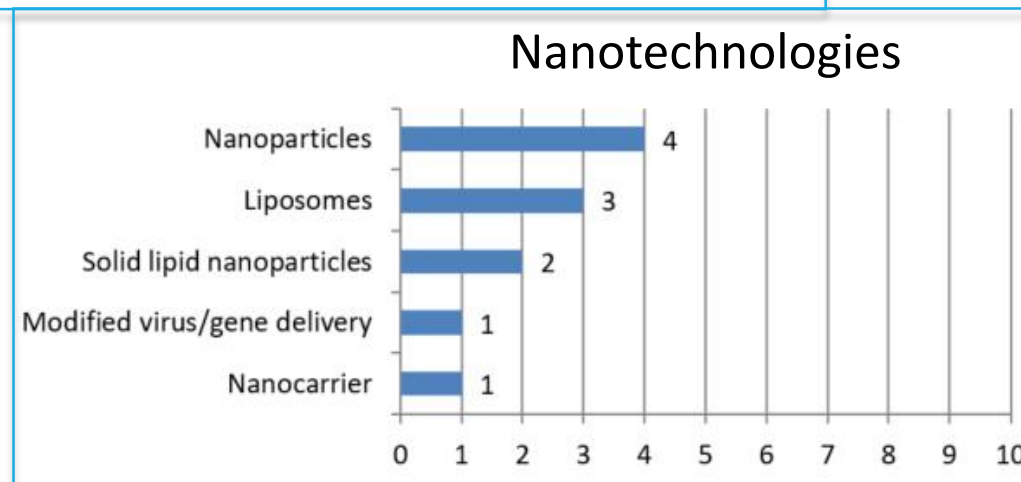
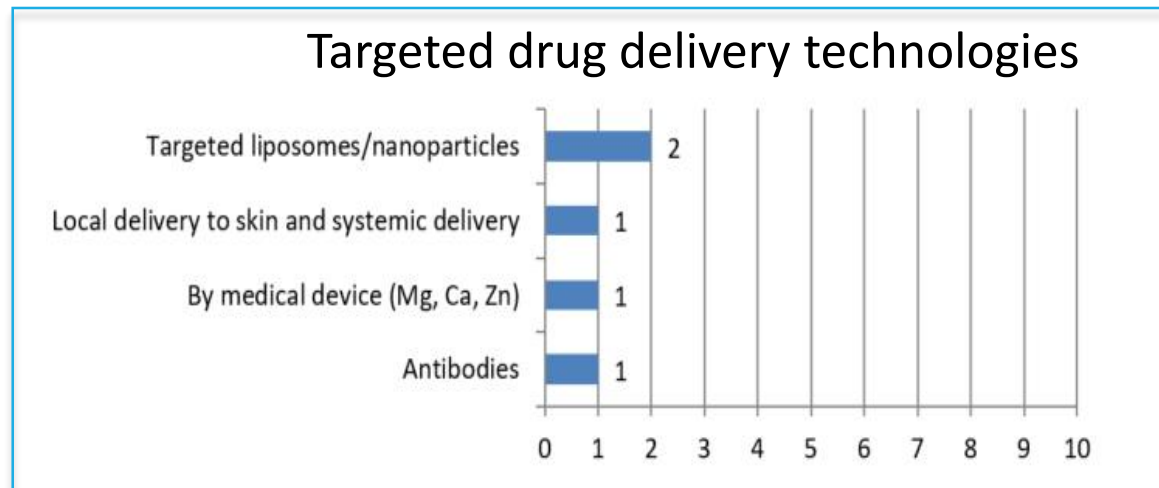


Modified release technologies:



Technologies offered by partner institutions

more specialized technologies



To summarise: Service Areas in Paediatric Formulations

**Advisory services for paediatric formulation
(and DEVICES)**

Pre-formulation assessments

**Conventional dosage form formulation
(oral & non-oral route)**

**Patient experience (taste masking) technology
and assessments**

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Services related to Medical Devices

Conclusions

Through this EPTRI paediatric formulation/device platform:

- **Many partners institutions** can offer several services and equipped facilities to the formulation thematic platform
- Activities could be grouped by **service areas** to facilitate access to stakeholders involved
- The **research platform** will serve to **match** experts able to provide/ deliver specialised service activities with research groups needing their services

to facilitate and enable timely and efficient formulation of suitable paediatric medicines



Thank you

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2nd – 3rd April 2020

