European Paediatric Formulation Initiative

Formulating better medicines for children

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Quick facts

=> Non profit organisation

=> Established in London (UK) in 2007 led by The School of Pharmacy

⇒ ~ 20 Members from industry, academia, hospital and regulatory agencies

www.eupfi.org
To promote and facilitate preparation of better & safer medicines for children through

- Sharing expertise and interactive discussion between industry, academia, clinical and regulatory professionals.
  - EMA observer
- Information dissemination
- Raising awareness (publications, conferences etc.)
- Linking and networking
  - IQ
  - SPeADD-UK (iUK) : tools for taste, acceptability and vitro/vivo correlation

EuPFI MISSION

EuPFI OBJECTIVES

1. **Identify** the issues and challenges - development of paediatric formulation & consider ways towards better medications and clinically relevant dosage forms for children

2. **Promote** early pharmaceutical consideration for development of paediatric medicines.

3. **Identify** potential information, knowledge, know-how gaps in the paediatric formulation development.

4. **Improve** the availability of information of paediatric formulations.

EuPFI-IQ, Mcersi-FDA workshop, June 2016
Annual Conferences

London, March 2009

Berlin, Sept 2010

Strasbourg, Sept 2011

Prague, Sept 2012

Barcelona, Sept 2013

Antwerp, Sept 2014

Lisbon, Sept 2016
**TASTE (MASKING & TESTING)**

**Etat des lieux** (Cram et al – 2009)

**Taste-Masking Technologies**
Approaches to taste masking (Walsh et al, 2015)

**Taste Assessment**
E-tongue interlab work (Pien et al, 2014)

**Acceptability/Preference**
Review on formulation factors affecting acceptability (Liu et al, 2015)

**Modification vs Manipulation of DF**
Standardization of types of paediatric pharmaceutical preps (Ernest et al, 2012)

**Risk/benefit framework**
Proposed for the selection of AAF (Sam et al, 2012)

**Key outputs**

**COLLABORATIVE OUTPUTS**
- IQ survey (EuPFI Athens 2014)
- Non-human tools for the evaluation of bitter APIs (SPeADD-UK)

**BCS Classification paed ?** (Batchelor et al, 2014, 2016)

**Review – paed biopharm method**
GAPS (Batchelor et al 2013)

**ADMINISTRATION DEVICES**
- Current devices challenges + recent developments (Walsh et al, 2012)
- Devices views/ experiences by EU HCPs (Walsh et al, 2015)

**BIOPHARMACEUTICS**

**ARCHIVE**

**AGE-APPRIOPRIATE FORMULATIONS**

**EXCIPIENTS**
3 Papers published
40 Excipients

**US PFI (NIH NICHD)**

**STEP database**
Safety & Toxicity of Excipients For Paediatrics

**GRiP**
Global Research in Paediatrics

**24/06/2016 EuPFI-IQ, Mcersi-FDA workshop, June 2016**
Current key priorities

AGE APPROPRIATE FORMULATIONS/ TASTE
- Palatability assessment of paediatric dosage forms /APIs (including in vitro methods)
- Dosage form acceptability, safety, efficacy and dose flexibility
- Modification of dosage forms
- Manufacturing challenges/Poorely soluble APIs

BIOPHARM
- Prioritise research - in paediatric biopharmaceutics
- Review strategies - bridging studies to support the development of paediatric medicines
- Review the impact of food on the predicted in vivo performance of paediatric medicines

EXCIPIENTS
- EXPAND STEP DATABASE
- Identify how excipients can affect the absorption of drugs and also affect GI physiology in children

ADMIN. DEVICES
- Survey – patients and carers on use of administratio n devices for children

24/06/2016 EuPFI-IQ, Mcersi-FDA workshop, June 2016
Initial discussion Oct. 2012...idea of a ‘paediatric symposium with FDA’
Oct. 2013...evolved into a transatlantic workshop since Dec. 2014

Bring together subject matter experts/key players/stakeholders in the field to find solutions to
- Acceptability assessment of paediatric dosage forms
- Derisking food/drink effects when administered with medicines and biopharm considerations
- Safety qualification of excipients for paediatric medicines

Harmonized Strategies
For more information read our article "European Paediatric Formulation Initiative - Formulating ideas for better medicines for children in the upcoming AAPS PharmSciTech Special Theme Issue on pediatrics dosage forms

Thanks to

M-Cersi
abbvie
Bristol-Myers Squibb
Lilly
BACK-UP SLIDES
AGE APPROPRIATE FORMULATIONS

- Dosage form acceptability, safety, efficacy and dose flexibility
- Food/drink effects on administration of medicines
- Safety and efficacy of co-administration
- Manufacturing challenges in developing paediatric formulations

Balancing of a quality target product profile against technical challenges and development feasibility
TASTE ASSESSMENT & TASTE MASKING

Bring together subject matter experts/key players/stakeholders in the fields of taste evaluation to propose a synopsis (guidance) for acceptable, sound, scientific approaches to address acceptability/palatability assessment of paediatric dosage forms.

Understand the current state of the art of taste masking technologies and platforms. Focus on the limitations and technology gaps (in formulation platforms suitable for different age ranges) and identify opportunities more effective age-appropriate taste masking technologies.

Understanding the current state of the art, and limitations, of taste assessment in vitro and in vivo methodologies.
PURPOSE:

Highlight all relevant aspects from specific development issues to appropriate standard laboratory test methods and methodologies for handling studies of such devices. In-depth literature research is performed to create an overview on the topic and to come up with guidance on requirements and feasibility.

CURRENT PRIORITIES:

- Evaluate current status of child appropriate administration devices.
- Get insight in devices test methods.
- Investigate requirements for handling studies.
- Develop a guideline
This reflection paper overview of currently available paediatric administration devices and highlights some of the challenges associated with, recommendations and recent developments in delivery devices exploratory survey provided some valuable insights into the views and experiences of European hospital doctors, nurses and pharmacists, regarding oral and respiratory administration devices for paediatric patients.
PURPOSE:
To address safety issues and problems associated with the excipients likely to be used in paediatric formulations.

CURRENT PRIORITIES:
- Safety & Toxicity of Excipients For Paediatrics
The STEP (Safety and Toxicity of Excipients for Paediatrics) database. Part 1—A need assessment study
Smita Salunke, George Giacola, Catherine Tuleu

The STEP database through the end-users eyes—USABILITY STUDY
Smita Salunke, Catherine Tuleu

Database launched OCT 2014
40 excipients
> 700 users
> 50 citations
PURPOSE:

Understand the current tools available to measure biopharmaceutical performance of paediatric medicines

Highlight the importance of additional research into paediatric biopharmaceutics

Undertake collaborative research to drive the development of age-appropriate in vitro tools that can be used to predict the in vivo performance of paediatric medicines
Review highlight several **knowledge gaps** in current methodologies in **paediatric biopharmaceutics** provide **recommendations based on existing knowledge** to adapt tests to better represent paediatric patient populations.

Note brings together some **key issues in direct extrapolation from adults into paediatric populations.**

explore how a paediatric BCS may differ to that in adults

**CURRENT PRIORITIES**

- Prioritise research activity to be undertaken in paediatric biopharmaceutics
- Review strategies currently used in bridging studies to support the development of paediatric medicines
- Review the impact of food on the predicted in vivo performance of paediatric medicines