CORE-MD

Coordinating Research and Evidence for Medical Devices

Consensus recommendations on a desirable policy for paediatric high-risk medical devices

Deliverable 2.5

Deliverable factsheet

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30/04/2023	0.2	Alan Fraser (ESC)	Draft final version after Coordinator's review
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01/09/2024	*1.1*	*Kathrin Gürlich, Bernadeta Patro-Golab, Berthold Koletzko (LMU/EAP), Alan Fraser (ESC)*	*Revised version incorporating comments received from the expert reviewers in the final review report, namely to align the final recommendations with the ones provided in D4.3.*

Acronyms and abbreviations

CHF	Child Health Foundation (Stiftung Kindergesundheit)
EAP	European Academy of Paediatrics
FDA	Food and Drug Administration
MDR	Medical Device Regulation

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Executive Summary

Regulatory requirements for medical device market approval in Europe have been recently changed by the EU Medical Device Regulation (MDR) (EU 2017/745) to enhance patient safety [1]. The necessity to obtain data from clinical investigation, high costs and long time for device evaluation and certification make it difficult for manufacturers to market high-risk medical devices, in particular those intended to be used in infants, children and adolescents.

Overall few medical devices are specifically intended for children as compared to adults, and the availability of innovative paediatric medical devices lags behind that of their adult counterparts [2]. Many barriers including those related to clinical characteristics, technical considerations, regulatory and ethical aspects and financial issues, hinder the development of paediatric medical devices [2]. The unique physiology of children and their rapid growth and development, as well as the required smaller size of a device and the device longevity complicate the development of medical devices for children. In addition, it is difficult to conduct sufficiently powered clinical studies, because sample sizes are small, events are rare and there is a lot of heterogeneity between paediatric patients. Furthermore, ethical aspects such as consent considerations and parental concerns can make recruitment of paediatric participant challenging. For manufacturers it may often not to be feasible and cost-effective to develop and evaluate new high-risk medical devices for children, or even to continue to market existing devices, because demand for medical devices in the paediatric age group is relatively low compared with adults.

All these factors combined may result in limited or delayed market access or withdrawal of essential high-risk medical devices for children, which raises concerns among European clinicians [3][4].

One of the Tasks within the CORE-MD project, led by the Child Health Foundation (CHF) (www.kindergesundheit.de) on behalf of the European Academy of Paediatrics (EAP), was to review methodologies applied in clinical investigation of high-risk medical devices specifically in children and to develop recommendations on paediatric medical device clinical investigation and to comment on approaches for evaluating them for market introduction.

In carrying out this task, we conducted a scoping review on the existing published evidence from clinical trials on high-risk medical devices in children to identify and describe methodologies applied in this research area. We concluded that within our assessed sample, clinical trials on high-risk medical devices in children were mainly multicenter, of various study designs, often without a concurrent control group, performed with small sample sizes and with a low number in young children and infants.

Additionally, CHF hosted an Expert Workshop on the clinical investigation and evaluation of medical devices for infants, children and adolescents on January 16, 2023 at the Dr. von Hauner Children's Hospital, LMU University of Munich, Germany, with a further virtual online meeting on March 23, 2023. We brought together a group of 18 experts from major paediatric clinical subspecialties, as well as a regulatory authority representative and an officer of the European Commission Directorate General

Health and Food Safety (DG SANTE). The workshop comprised presentations on the paediatric device context, the CORE-MD project, the EU MDR, and the results of our scoping review. The experts agreed that mechanisms to ensure the continued availability of medical devices needed in limited numbers of patients e.g. for infants, children and adolescents, should be established. Consensus recommendations on aspects of clinical evaluation of high-risk medical devices in children, as well as on clinical investigation have been developed.

Manuscripts on the scoping review as well as on the consensus recommendations have been prepared and published in paediatric scientific journals.

1 Introduction

The first aim of Task 2.4 was to review existing published evidence on the clinical investigation of high-risk medical devices in children in order to identify and describe previously applied approaches and methodologies in this research area. Ultimately, obtained findings were to contribute to other outcomes within this task.

The second aim was to establish a paediatric expert panel and to organize a workshop with the paediatric experts to develop consensus recommendations for appropriate methodologies for clinical investigation of high-risk medical devices for use in children and to comment on approaches for evaluating medical devices for market introduction.

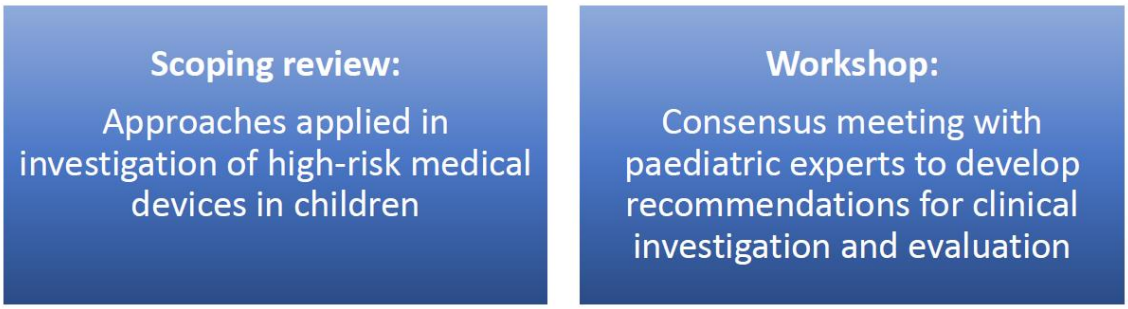

Figure 1. Aims of Task 2.4

2 Scoping Review

2.1 Objective

The objective of the review was to summarize the existing current published evidence from clinical trials on high-risk medical devices in children to identify and describe methodologies applied in this research area.

2.2 Methods

As our research question is quite broad, of a more explanatory character, scoping review was agreed upon as the most appropriate review design to apply [5]. The PRISMA Checklist for Scoping Reviews (Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews) [6] and the methodology of the Joanna Briggs Institute's (JBI) Reviewers' Manual [7] were followed.

We developed a review protocol which was registered and published on the Open Science Framework (available under https://osf.io/uzekt and in Appendix 1).

We included clinical trials of any study design involving paediatric populations covering the age range from birth to 21 years. Mixed populations including both children and adults were also eligible. We focused our interest on the clinical fields of diabetology, cardiology, orthopaedics and surgery. We included trials on class III medical devices according to the U.S. Food and Drug Administration (FDA), and implantable and class III medical devices according to the MDR. As there is no central database of (paediatric) medical devices available in Europe, we developed a list of high-risk medical devices with paediatric age indications based on the FDA sources. Based on the list of identified high-risk medical devices, we developed the search strategy with the assistance of an information specialist. We searched two medical databases: Embase (Ovid) and Medline (PubMed). Our search timeframe was from beginning of January 2017 to beginning of November 2022.

2.3 Results and conclusions

We identified 1692 records in our search. After deduplication we did title and abstract screening for 1471 records and fulltext screening for 186 records. Within the assessed sample, clinical trials on high-risk medical devices in infants, children and adolescents were mostly multicenter studies conducted in Europe and North America. Various study designs were used, often without a concurrent control group. Almost 90% of the trials were evaluating devices for Type 1 Diabetes. In our sample clinical trials were performed mostly with small sample sizes and mostly in adolescents or older children, with a low number in infants and young children.

2.4 Manuscript

We compiled the results and conclusions of the scoping review in a report and shared it with our established paediatric expert panel. We prepared a manuscript that has been published: Guerlich K, Patro-Golab B, Dworakowski P, Fraser AG, Kammermeier M, Melvin T, Koletzko B.. Evidence from clinical trials on high-risk medical devices in children: a scoping review. Pediatric research 2024 Feb, 95(3), 615–624. https://doi.org/10.1038/s41390-023-02819-4.

The manuscript it also available in the library of the CORE-MD website at the following link: https://www.core-md.eu/wp-content/uploads/2023/10/Gurlich_Trials-Pediatr-Med-Dev_Ped-Res23.pdf.

3 Paediatric Expert Workshop and consensus recommendations

3.1 Paediatric Expert Panel

We established a mulit-stakeholder expert panel with 18 paediatric experts from the major paediatric subspecialities and paediatric surgery, a regulatory authority representative and an officer of the European Commission Directorate General Health and Food Safety (DG SANTE). To establish the panel, we systematically explored collaboration networks of EAP and Core-MD consortium members to identify relevant paediatric experts. We generated a contact list of potential paediatric experts and advisors as well as important and relevant paediatric societies. Invitation letters were sent out at the end of July 2022. The response rate was good and we reached a satisfactory distribution of countries across Europe, as well as a good balance of relevant clinical fields.

3.2 Key questions

In preparation for the workshop, key questions were shared with the experts by email in advance, which served as a framework for the discussions during the workshop.

- What kind of evidence would you like to see for high-risk medical devices for infants, children and adolescents (particularly those devices you work with) to document suitability, benefit, and safety? Would you propose different approaches for established devices with pre-existing clinical experience, vs. new devices?
- With respect to high-risk medical devices for infants, children and adolescents (particularly those devices you work with) what kind/level of clinical investigation do you consider practically feasible?
- Which cutoff is appropriate to define an exemption rule for recognition of “orphan medical devices” in the EU?
- What would you propose as a strategy for marketing authorization of high-risk medical devices for patients in the paediatric age group (or of „orphan medical devices“) that provides a balance between assurance of performance and safety and the goal to enable access of the vulnerable patient group to critical medical devices?

3.3 Consensus Workshop

The consensus workshop was hosted on January 16, 2023 at the Dr. von Hauner Children’s Hospital, LMU University of Munich, Germany, followed up by a further virtual online meeting on March 23, 2023.

The objectives of the workshop were to develop recommendations for appropriate methodologies for the clinical investigation of high-risk medical devices for use in children and to comment on approaches for the evaluation and certification of medical devices for market introduction that do not inappropriately

reduce device availability for sick children. The workshop comprised presentations on the paediatric device context, the CORE-MD project, the EU MDR, and the results of our scoping review. The agenda of the workshop can be found in Appendix 2.

The experts agreed that the rights of children for the highest attainable standard of health laid down in the United Nations Convention on the Rights of the Child [8] need to be fully respected. Regulatory mechanisms, similar to those existing for paediatric medicines, to ensure the continued availability of medical devices needed in limited numbers of patients e.g. for infants, children and adolescents, need to be established.

The experts agreed on key aspects of clinical evaluation and clinical investigation of high-risk medical devices in children, and developed recommendations accordingly. Selected ethical aspects of clinical investigation of medical devices in children were also addressed. It was agreed upon that the evaluation of high-risk medical devices should include competent paediatric experts as part of a paediatric medical device expert panel. The experts emphasized the need for transparency of clinical evidence supporting medical device evaluation and proposed criteria for the designation of an “orphan medical device” status. Finally, the approach to clinical investigation of high-risk medical devices tailored to clinical context, following established hierarchy of evidence, and taking into account the feasibility of obtaining clinical evidence for medical devices used in children was proposed.

The conclusions from the workshop were to recommend study designs in this order:

1. Randomised controlled trial (the highest level of evidence)

2. Comparative prospective study with concurrent controls (experimental or observational)

3. Comparative study without concurrent controls (for example with historical control)

4. Prospective case series with documentation of either post-test or pre-test/post-test outcomes.

These expert recommendations refer to a widely accepted hierarchy of evidence, published from Australia and offered as guidance by their regulatory authority, the Therapeutic Goods Administration [9]. That hierarchy, together with other relevant guidance, was reviewed in detail by the CORE-MD consortium in Task 1.4 and published in its project deliverable D1.6.

The conclusions from the CORE-MD consortium, concerning the design of studies for medical devices, were developed in another workshop and published as project deliverable D4.3 (“Recommendations for a hierarchy of clinical evidence for high-risk medical devices”). That report includes a table (see Example 1, at page 18) with special recommendations for clinical investigations of an innovative or orphan medical device, that are relevant too for devices used in children.

The recommendations from the CORE-MD Paediatric Expert Workshop are in concordance with the later general recommendations in D4.3. They provide more details, taking into account the different stages of clinical investigation that can be applied to any orphan device. Specifically for paediatric medical devices,

extrapolation of data from trials in adults and mixed population studies involving both adults and children can additionally be considered.

Figure 2. Group picture of the paediatric expert workshop

3.4 Manuscript

All information that have been generated and all consensus recommendations that have been developed during the workshop were summarized in a manuscript that has been published and presented in several relevant scientific and regulatory fora (see Final Dissemination Report, D4.8).

Here is the article's reference and open access link:

Guerlich K, Patro-Golab B, Barnacle A, Baumann U, Eicken A, Fraser AG, Gruszfeld D, Haas NA, Jonker AH, Kammermeier M, Kenny D, Kolaček S, Lapatto R, Maconochie I, Mader S, McGauran G, Melvin T, Muensterer O, Piscoi P, Romano A, Saxena AK, Schneider DT, Turner MA, Walle JV, Koletzko B; European Academy of Paediatrics. European expert recommendations on clinical investigation and evaluation of high-risk medical devices for children. Acta Paediatrica. 2023; 112: 2440–2448. https://doi.org/10.1111/apa.16919.

4 Summary and conclusions

We conducted a scoping review on the existing published evidence from clinical trials on high-risk medical devices in children to identify and describe previously applied approaches and methodologies in this research area.

We established a paediatric expert panel and invited the members to a joint workshop where consensus recommendations on aspects of clinical evaluation of high-risk medical devices in children, as well as on clinical investigation have been developed.

Two manuscripts on the scoping review and the consensus recommendations have been published in international paediatric scientific journals.

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[8] United Nations General Assembly. Convention on the Rights of the Child. Resolution 25, session 44. New York: The Office of the United Nations High Commissioner for Human Rights (OHCHR) November 20, 1989.

[9] National Health and Medical Research Council (NHMRC). NHMRC additional levels of evidence and grades for recommendations for developers of guidelines Stage 2 Consultation Early 2008 – end June 2009. https://www.mja.com.au/sites/default/files/NHMRC.levels.of.evidence.2008-09.pdf. Accessed 21 August 2024.

Appendices

A.1 Appendix 1 – Review Protocol

The Review Protocol was registered and published at the Open Science Framework and is attached on the following pages:

Kathrin Guerlich, Bernadeta Patro-Golab, Michael Kammermeier, Paulina Dworakowski, Berthold Koletzko (2022) Clinical evidence for high-risk medical devices in children: A protocol for a scoping review. https://osf.io/uzekt

Clinical evidence for high-risk medical devices in children: A protocol for a scoping review

Source Activity: CORE-MD, Work package 2, Task 2.4
Authors: Kathrin Guerlich[1,2*], Bernadeta Patro-Golab[2*], Michael Kammermeier[2], Paulina Dworakowski[3], Berthold Koletzko[1,2,4], LMU Munich, on behalf of the European Academy of Paediatrics

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Background

A key aim of the EU Medical Device Regulation (EU 2017/745; MDR; https://eur-lex.europa.eu/eli/reg/2017/745/oj) is to enhance the safety for patients requiring high-risk medical devices by increasing the regulatory requirements for evidence-based clinical evaluation of marketed medical devices in Europe. After the transition period ending on 26 May 2024, with the recent proposal for an extension to 2027 (1), products marketed in the EU that were approved under the previous rules, as well as newly developed products, will need to comply with the new regulation (2). However, meeting these increased regulatory requirements is challenging particularly for devices for patients in the paediatric age group for several reasons,.

Among important contributory factors is the relatively low demand for high-risk medical devices in this age group (3). It may not be feasible and cost-effective for manufacturers of medical devices to develop, evaluate and produce new medical devices for infants and children, or even to resubmit and continue to market existing devices when considering that the market for medical devices for the paediatric age group tends to be small and hence the likelihood for achieving a return of the investment for evaluation and registration may be low. Furthermore, it is difficult to conduct adequately powered clinical trials evaluating medical devices in children and to obtain validated findings due to the limited number of patients available, the rarity of events, and the very heterogeneous patient population ranging from very small preterm infants to adolescents (4). Additionally, both ethical and parental concerns can make recruitment and enrolment of participants more difficult (5). Together, these may result in withdrawal and limited or delayed market introduction of innovative medical devices for children, which raise major and also ethical concerns regarding a possible lack of access to necessary and life-saving interventions with required medical devices in infants, children and adolescents.

Most of the high-risk medical devices used in children have not been approved for their use in this population (6), but were studied and approved solely in participants 18 years or older (7). As medical devices with specific approval for paediatric use are often unavailable, off-label use of adult versions of medical devices is widespread, despite little to no evidence documenting the suitability and safety of their use in younger age groups (6, 8). Information about the safety and efficacy of medical devices in children is largely derived from the experience and expertise of paediatricians, from evidence in adult populations, and partly from pre-clinical evaluation (4). However, since children have special physiological and disease conditions, and resulting

medical needs, off-label use can be a problematic path, with the potential for increased risks of associated adverse events in this group (9).

While obtaining the best possible documentation of safety and efficacy of medical devices in children is a desirable goal, at the same time enabling access to innovative medical devices and related state of the art and potentially life-saving interventions for the youngest patients is equally important. To address the challenges arising from this dilemma and to protect the availability of paediatric medical devices, it is necessary to develop a broadly agreed evidence-based regulatory policy for paediatric medical devices.

The project "Coordinating Research and Evidence for Medical Devices" (CORE–MD; https://www.core-md.eu/) is a EU funded Horizon 2020 project that aims to "review methodologies of clinical investigations, advise on study designs, and develop recommendations for aggregating clinical data from registries and other real-world sources" (3). One of the project objectives is to evaluate the existing evidence for high-risk medical devices specifically in children. Obtained findings will serve as a basis for formulating recommendations on the evaluation and registration of medical devices for infants, children and adolescents in the European Union, with the ultimate goal of optimizing the therapeutic benefits from their use in the future.

Objectives

As CORE-MD consortium partners, we aim to review existing published clinical evidence on high-risk medical devices, namely available evidence from clinical trials, in children in order to identify and describe methodologies applied in this research area.

Methods

Given our broad review questions and thus the exploratory character of the review, we will conduct a scoping review, an approach recommended when the purpose of the review is to "scope a body of literature, clarify concepts or to investigate research conduct" (10). Scoping reviews allow for more expansive inclusion criteria and are typically used to provide an overview and map of the available evidence in a given field and to identify knowledge gaps (10).

This scoping review will be conducted and reported in accordance with the methodology of the Joanna Briggs Institute's (JBI) Reviewers' Manual (11) and with the PRISMA-ScR guidelines (12) (Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for

Scoping Reviews) for a transparent procedure and reporting. The protocol will be published on the website of the CORE-MD consortium (https://www.core-md.eu/) and registered at the Open Science Framework (https://osf.io/).

Inclusion and exclusion criteria

Participants

The study population of interest will be children from different age-groups covering the range from 0 to 21 years, including preterms, neonates, infants, toddlers, children and adolescents, with any medical condition as an indication for the use of specific medical device. Mixed population studies that involve both children and adults will also be included.

Concept

Medical devices, including paediatric medical devices, are categorized in different risk classes according to the new EU Medical Device Regulation (MDR) as well as to U.S. Food and Drug Administration, FDA regulation. However the classification rules are different and some products may fall into different risk classifications. The focus of this review will be on high-risk medical devices. Therefore, studies on class III medical devices according to FDA and on class III and IIb medical devices according to the MDR regulation, which corresponds with the highest risk classification, will be eligible for inclusion.

For feasibility reasons, we will focus on selected medical devices, based on the pre-defined list of high-risk paediatric medical devices, from the following clinical specialties: cardiology, diabetology, orthopaedics and surgery. This selection is in line with the similar reviews done by the CORE-MD consortium for adult population (13-15) and covers clinical specialties (cardiology and clinical chemistry that includes insulin pumps and glucose sensors) that are frequently represented among approved devices in children (9). As in Europe medical devices are not fully tracked or summarized centrally, we will develop the list of devices of interest primarily based on the FDA products listings.

We will use the existing device list of Lee et al. (9), who identified all high-risk medical devices with paediatric age indications listed in the FDA PMA database from inception to February 2020 in their study.

Additionally, we will supplement this list by searching the following FDA resources:

- Premarket Approvals (PMA) database: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pmasimplesearch.cfm (from March 2020 to June 2022)
- Annual Reports to Congress on Premarket Approval of Paediatric Uses of Devices, covering approved PMA and Humanitarian Device Exemption (HDE) applications (available from 2008 to 2017)
- Humanitarian Device Exemption (HDE) database (from 2018 to June 2022)

In this scoping review we will investigate designs and methods that have been used so far in clinical trials with the use of a high-risk medical device in children as an intervention.

Due to the nature of review, the list of outcomes of interest will remain open but will include the following:

- Country (single- vs. multicentre, national or international)
- Funding (industry sponsored, investigator initiated)
- Type of clinical investigation: pre- or post-market clinical investigation
- Study design (e.g. controlled clinical trials, crossover trials, single-arm interventional studies)
- Sample size and proportion of paediatric participants
- Target population characteristics (age, sex)
- Type of device and indication for its use
- Assessed study outcomes, including safety, performance, efficacy, patient reported outcomes

Context

We will include any clinical trials' reports on paediatric high-risk medical devices, including those on pre- and post-market clinical investigation. No restrictions will be applied in terms of study setting or device indications for use, with areas of application including cardiology, diabetology, orthopaedics and surgery for original studies.

Types of sources

Clinical trials of any design (e.g. randomized and non-randomized controlled clinical trials, interventional studies without concurrent controls, before–after studies, crossover trials) will be eligible for inclusion. Qualitative studies focused on the intervention being trialled will be

also considered for inclusion. Conference abstracts, commentaries, editorials, letters, book chapters will be excluded.
As the aim of this review is to provide an overview of the type of available evidence, which we believe does not require the totality of evidence, and we are interested in the current situation, we will limit our search to the most recent reports, covering the last 5 years.

Search Strategy

We will search the following electronic medical databases: MEDLINE (PubMed) and Embase. Database-specific search strategies will be developed based on the predefined list of high-risk medical devices, with the use of trade and generic devices' names.

The timeframe for our search will be from January 2017 to October 2022. We will restrict our search to sources and papers published in English language only. The detailed search strategy will be provided.

Literature selection

Records identified after applying our search strategy will be uploaded into reference manager EndNote (Version X8) and duplicates will be removed. Titles and abstracts will be screened against the inclusion criteria by one reviewer (16). Full text articles will be obtained for abstracts that need to be included or appear unclear. They will be independently evaluated by two reviewers. Any disagreements regarding inclusion will be resolved through discussion and in case of disagreement discussed with a third independent reviewer. Reasons for exclusion will be recorded. A PRISMA flow diagram of the selection process will be prepared.

Data Extraction

Data extraction will be performed manually for each included article using a pre-specified data extraction form. The second reviewer will independently perform a duplicate extraction. We will extract information on authors, year of publication, study setting, funding, study aim and design, type of investigation, study sample size, participant demographic characteristics (age, sex), medical device characteristics (trade and generic name, medical condition the device is intended for) and assessed study outcomes. Any disagreements between the reviewers will be discussed and in case of disagreement settled by a third reviewer.

Data analysis

We will use basic descriptive statistics (e.g. frequencies, proportions) to characterize the study designs, the study sample sizes and proportion of paediatric participants within the study sample, the study setting and population characteristics (with main emphasis on age groups), the type of devices and their distribution across studied clinical specialties, assessed study outcomes and sources of funding. We will consider exploring differences in the applied methodologies based on the age group of study participants and their medical conditions for which the use of medical device is intended. We will use tables and charts to present the findings, however other formats may be considered after data extraction, if appropriate.

Acknowledgements

We are grateful to all CORE-MD consortium members, in particular Prof. Alan Fraser and Dr. Tom Melvin, who provided us with important insights into regulatory research, critical comments/review of this protocol and overall support to perform this project Task.

We thank Dr. Benjamin Glicksberg and his co-authors for sharing with us the list of paediatric devices identified in the study by Lee et al. (9), for the purpose of this review. We also thank the members of the European Commission Medical Device Coordination Group Task Force on Orphan Devices for helpful discussions and comments.

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A.2 Appendix 2 – Workshop Agenda

CORE-MD
Coordinating Research and Evidence for Medical Devices

Paediatric Expert Workshop – Agenda
16/01/2023, 10:30 – 16:00 CET

LMU Klinikum, Dr. von Hauner Children's Hospital
Lindwurmstr. 4, 80337 Munich
"Seminarraum 5"

Time	**Sessions**	Presenter
10:30 – 11:15	**Welcome and introduction round**	Berthold Koletzko (EAP), all
11:15 – 11:30	**The CORE-MD Project – Background and objectives**	Alan Fraser (ESC)
11:30 – 11:45	**Commission proposal for the amendment of the transitional provisions of the EU MDR**	Paul Piscoi (EC, DG SANTE)
11:45 – 12:15	**Clinical evidence for high risk medical devices in children: A scoping review**	Kathrin Gürlich (EAP) Bernadeta Patro-Golab (EAP)
12:15 – 12:30	**Developing conclusions**	Berthold Koletzko (EAP)
12:30 – 13:15	**Lunch**	
13:15 – 14:45	**Open discussion**	All
14:45 – 15:00	**Coffee break**	
15:00 – 15:45	**Open discussion**	All
15:45 – 16:00	**Conclusions and next steps**	Berthold Koletzko (EAP) Alan Fraser (ESC)

A.3 Appendix 3 - Open letter to Commissioner Stella Kyriakides

Following the dissemination of the results exposed in the present deliverable and related scientific articles, the representatives of 22 European medical associations dedicated to child health care have formulated their joint position on appropriate approaches for the clinical investigation and conformity assessment of high-risk medical devices for children as part of the CORE-MD project.

Based on these considerations, on June 27th, 2023, the CORE-MD consortium as well as leading Scientific Societies and Medical Associations have issued a call for action to Commissionner Kyriakides (with the EAP, leader of CORE-MD Task 2.4, as the leading signatory) to ensure that children and patients with orphan diseases will have continued access to medical devices that are needed for 'state of the art' health care.

Here is the link to the article featuring this important advocacy initiative in the CORE-MD website: https://www.core-md.eu/open-letter-to-commissioner-stella-kyriakides-to-secure-access-to-essential-medical-devices-for-children/. The full text of the letter is also available here: https://www.core-md.eu/wp-content/uploads/2023/06/Letter-Kyriakides_Med-Devices-signed-270623.pdf.

On September 4th, 2023, the Cabinet of the President of the European Commission has sent a formal answer to the above mentioned letter reiterating that the European Commission is committed to finding solutions for the availability of critical medical devices, in particular those used for the treatment of children, in order to maintain a high level of patient care in Europe.

CORE-MD

CORE-MD, Coordinating Research and Evidence for Medical Devices, aims to translate expert scientific and clinical evidence on study designs for evaluating high-risk medical devices into advice for EU regulators.

For more information, visit: www.core-md.eu

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