EPTRI
European Paediatric Translational Research Infrastructure

EPTRI SCIENTIFIC MEETING

BOOK OF ABSTRACTS

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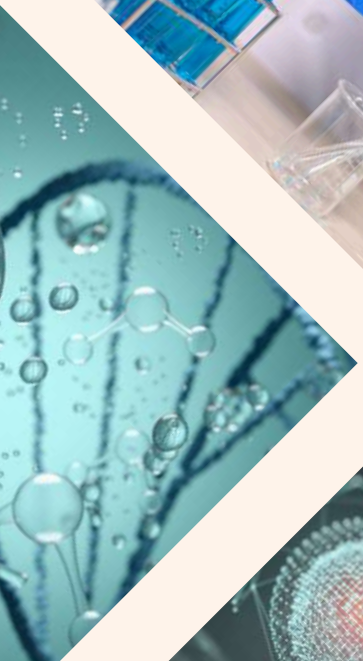

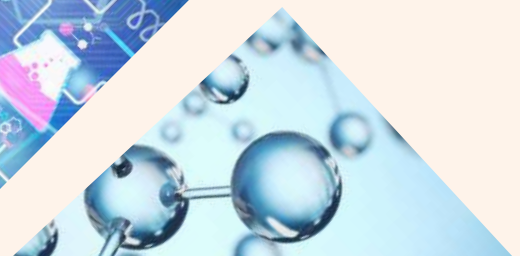

“Enhancing Paediatric Medical Devices in Europe”

SPEAKER SECTION

SPEAKER: JANA RUSSO

Paediatric and orphan devices under MDR – manufacturers’ perspective

The European Medical devices regulation 2017/745 (MDR) does not provide specific pathways to the European market for orphan or paediatric devices. The MDCG 2024-10 is a step in the right direction, providing criteria on how to classify an orphan device and allowing specific considerations for applying the MDR concept of clinical evidence to orphan devices. However, orphan devices continue to face challenges in reaching the European patients. These are related to the overall inefficiencies of the current system, such as unpredictability of conformity assessment in terms of timelines and costs as well as high administrative burden created by the MDR. In that connection, recent MedTech Europe survey data<https://www.medtecheurope.org/resource-library/medtech-europe-2024-regulatory-survey-key-findings-and-insights/> shows that a significant number of orphan device manufacturers plan reductions to their orphan devices portfolio under MDR. In order to put in place a specific orphan devices’ pathway as well as to deliver on the overall goals of MDR and IVDR (EU 2017/746), the MedTech regulatory system needs a dedicated governance structure. In addition, orphan device manufacturers need support in terms of financial incentives to be able to re-invest into orphan devices’ production.

SPEAKER: ANNELIENE JONKER

DeCODe: Develop Child and Orphan Device Support

The journey of each baby, child or young person living with a rare disease or severe or complex condition depends on medical devices for their diagnosis, treatment, and care. The average patient in a hospital has 10-15 medical devices around their hospital bed, which increases exponentially with the severity or complexity of the disease. The development of these technologies, the so-called paediatric and orphan medical devices, is slowly gaining much-needed attention. The recent development of the first guidance for the development of orphan devices has, as such, been a significant step forward in the rare diseases landscape. However, while the importance of paediatric and orphan medical devices has been acknowledged, there is a significant unmet need for paediatric and orphan medical devices, specifically those for babies and small children, and there is a high need to stimulate the development of novel or adapted paediatric and orphan medical devices.

To support paediatric and orphan medical device developers, the DeCODe consortium, co-funded by the European Commission, represents a ground-breaking initiative aimed at catalysing device innovation. This collaborative group, comprising clinicians, researchers, industry experts, and regulatory authorities, develops a pivotal platform for developing safe and effective paediatric and orphan medical devices. It will do so to accelerate the development of novel, innovative paediatric and orphan medical device solutions at all stages of the product lifecycle towards implementation. It will map paediatric and orphan medical device stakeholders and initiatives and develop a critical pathway analysis for the optimal development of novel paediatric orphan medical technologies. In

spring 2025, an open call will be held for paediatric medical device stakeholders to apply for support for their use cases. Use cases are meticulously selected based on their medical significance, feasibility, and potential impact. Technical assistance is provided to use cases' applicants, including guidance on device design, engineering, and regulatory compliance tailored to the paediatric population.
By uniting the diverse expertise of the consortium, DeCODe aims to facilitate the innovation of developers and surmount regulatory challenges. Ultimately, DeCODe aims to accelerate the development of essential medical devices that enhance and transform the quality of care for our children living with rare diseases.

SPEAKER: SOFIA FERREIRA QUARTINO

i4KIDS 4RARE – From Challenge to Adoption: Acceleration of Paediatric Orphan Medical Devices

Background: Children represent 25% of the world's population, yet there is a significant gap in medical innovation between adult and paediatric care. Factors such as perceived risk, limited market size, regulatory complexity and diffusion of paediatric expertise have hindered investment in paediatric healthcare. Rare diseases, which affect approximately 8% of the world's children, often lack dedicated medical products due to these challenges. In particular, there are an estimated 7,000 to 8,000 rare diseases affecting approximately 400 million people worldwide, with only 5% receiving specific treatments.

Objective: The i4KIDS-4RARE initiative aims to bridge this gap by developing and implementing a specialized accelerator program. This program is dedicated to fostering the creation and advancement of innovative solutions tailored for paediatric patients with rare diseases, particularly in areas with unmet medical needs.

Methods: The accelerator program focuses on three critical domains:

1. **Paediatric Cardiology:** Accelerating the development of a device to monitor patients during complex surgeries for congenital heart disease.
2. **Paediatric Rehabilitation:** Developing a home rehabilitation platform for children with spinal muscular atrophy (SMA).
3. **Paediatric Neurology:** Launching a challenge-based program for rare paediatric epilepsy (Epicare).

The program provides a structured framework, essential resources, mentorship, and financial support to innovators, researchers, and healthcare professionals. By fostering a supportive ecosystem that encourages multidisciplinary collaboration, knowledge exchange, and cross-sector partnerships, i4KIDS-4RARE aims to transform breakthrough ideas into tangible solutions.

Expected Outcomes: Through strategic partnerships with the European Reference Network (ERN), healthcare organizations, and industry experts, i4KIDS-4RARE seeks to facilitate collaborative research, development, and validation of novel orphan medical devices. This initiative addresses the medical, research, and social needs of paediatric patients with rare diseases, ensuring they receive accurate diagnoses and appropriate treatments.

Conclusion: i4KIDS-4RARE represents a pioneering effort to accelerate the development of orphan medical devices for children with rare diseases, aiming to improve their quality of life and bridge the existing gap in paediatric healthcare innovation.

SPEAKER: SANDRA BRASIL

Medical Devices and Digital Health Solutions for Paediatric and Rare Diseases.

Authors: Sandra Brasil[1], Eleonora Sarracco[1], Donato Bonifazi[1], Anneliene Jonker[2]

1 – European Paediatric Translational Research Infrastructure (EPTRI), 2 – Health Technology and Services Research (HTSR) group, University of Twente.

Abstract: Background: The medical devices (MDs) field has expanded during the last years, leading to innovative medical solutions and significantly improving patient care, however, MDs are mainly developed for the adult population, while paediatric applications rely on MDs repurposing and/ or adaptation lacking consideration for changes in disease features, growth development and hormonal changes. There is a lack of approved MDs labelled specifically for paediatric use and designed and developed specifically for children and young adults. A large gap still exists between the conceptual idea and the final clinical application for paediatric devices, mostly due to the significant development costs and regulatory efforts required, hindering Europe's competitiveness in MD development particularly in small population areas. In the EU, medical devices are regulated by the new Regulation (EU) 2017/745, entered into force in May 2021. Fostering the development of MDs tailored to children's needs, is a multidisciplinary challenge and requires different expertise, competencies, methods and technologies. In almost all cases, MDs need to be available in various sizes and configurations due to variations in the patient's anthropometric dimensions. Depending on the paediatric age groups that are targeted by a given MD, research protocols should plan to recruit and enrol enough participants to ensure uniform distribution across the age spectrum. Many of the protocols will depend on the MD's intended use and whether it is being used to diagnose, manage a temporary or permanent disease state, treat an injury, or correct a condition. Hence, there is the need to maintain a constant collaborative approach with patients and families that represent the final users and the key actor of any paediatric research services including those on MDs.

Objectives: We propose to develop a platform linking different stakeholders, such as researchers, clinicians, patients's families and representatives and SMEs to promote the exchange of expertise needed to the swift development and market access to MDs specifically tailored to the paediatric population. This platform will provide expertise on: **i)** Design and development of MDs from the concept of the idea with the related analysis to the performance studies; **ii)** Prototype design and risks analysis including safety risks (mechanical, electrical, electronic or non-clinical toxicological testing); **iii)** Medical device validation to provide evidence that device specifications conform with user needs and their

intended use; **iv)** End-user/usability assessment to enable a medical device design team to improve the usability of their devices.

Conclusion: By combining expertise from different areas and providing a multi-disciplinary stakeholder network, our proposal will break down fragmentation between various disciplines of medicine and technological areas in order to conceive and develop tailored, patient-centred, safer and integrated MDs that can seamlessly be introduced in healthcare systems.

SPEAKER: GIOVANNI TRISOLINO

Virtual Surgical Planning and 3D-Printing of Personalized surgical devices for children with rare bone diseases.

Giovanni Trisolino[1], Grazia Chiara Menozzi[1], Giulia Alessandri[1]

1 – IRCCS ISTITUTO ORTOPEDICO RIZZOLI BOLOGNA

Background: Virtual reality and 3D printing are revolutionizing orthopedic surgery by enabling virtual surgical planning (VSP) and patient-specific instruments (PSIs) to enhance precision and reduce costs. Our hospital has established an in-office 3D printing Point of Care (3DP-PoC) using cost-effective Fused Deposition Modeling (FDM) with Polylactic Acid (PLA) to produce PSIs. This study presents preliminary results of the 3DP-PoC program for treating pediatric skeletal deformities.

Methods: We assessed the safety and efficacy of ann-HTPLA 3D-printed PSIs for pediatric limb deformity correction. Low-dose CT scans were used for imaging, followed by segmentation (Mimics, Materialise 26.0) and conversion into 3D models (STL format). These models improved tactile understanding, surgical planning, and communication with surgeons, residents, and families. Surgical simulation was performed in a non-immersive virtual environment, evaluating deformity correction, osteotomy planning, and fixation selection.

Results: Since 2018, 145 skeletal segments in 117 patients (including 15 oncology cases) have been treated with VSP. In 52 patients (75 segments), 3D-printed PSIs were used (158 total). These PSIs ranged from 3.8 cm^3 to 58.8 cm^3, with 95.2% demonstrating effective use.

Additionally, 47 bone grafts were shaped, including 39 homologous donor grafts—13 pre-shaped in a clean room and 26 shaped intraoperatively. PSI-assisted procedures were on average 45 minutes shorter and required fewer fluoroscopy shots. Optimal correction was achieved in 37% of cases, while 41% had under-corrections and 22% had over-corrections. Major complications occurred in 13.8% of patients, including 4.3% infections. Intraoperative use of 3D-printed PSIs did not increase infection rates or other complications.

Conclusions: In-office 3D printing is proving to be a valuable tool for pediatric limb deformity correction. Ann-HTPLA PSIs demonstrated high usability and safety, supporting their role in cost-effective surgical planning. Further research is needed to refine correction accuracy and optimize patient outcome.

SPEAKER: ILONA MERTELSEDER

Issues in paediatric fracture management

Ilona Mertelseder[1], Annelie-Martina Weinberg[1]

1 – Department of Orthopaedics and Traumatology, Medical University of Graz

Managing pediatric fractures is challenging, especially when the growth plate (physis) is involved. Implant selection must minimize interference with skeletal development. Preserving the physis is crucial to preventing limb length discrepancies and angular deformities, which may require correction. But also the composition need to be healthy to avoid long-term complications. Conventional fixation methods avoid transphyseal implantation of non-resorbable materials, such as stainless steel or titanium, to prevent premature closure, though this may compromise stabilization. The high stiffness of these materials (high Young's modulus relative to bone) can induce stress shielding, weakening adjacent bone and increasing refracture risk. Additionally, implant removal is necessary due to material precipitates, adding to the patient's burden.

Biodegradable materials, particularly magnesium (Mg)-based alloys, are promising alternatives. Mg alloys have a Young's modulus closer to bone, reducing stress shielding. Their controlled degradation in vivo allows temporary stabilization without removal, which is beneficial in pediatric applications where retained implants may disrupt skeletal growth. Additionally, degradation products support bone healing.

ZX00, a magnesium-based alloy containing <0.5 wt% zinc (Zn) and <0.5 wt% calcium (Ca), is a promising pediatric fracture fixation option. Magnesium promotes osteogenesis and mineralization, supporting bone formation. Calcium enhances osteoblast adhesion and proliferation, facilitating bone-implant integration. Zinc improves corrosion resistance, controlling degradation and maintaining mechanical integrity during early healing. Implant degrades over time, removing the need for hardware removal surgery.

In transphyseal applications, uncontrolled degradation may cause growth disturbances similar to those observed with conventional materials. Therefore, precise control over degradation kinetics is crucial to ensuring biomechanical support during healing.

We studied eight three-month-old female juvenile sheep, implanting monocortical ZX00 screws in the right tibial epiphysis. The left tibia received a titanium (Ti) screw or remained untreated as a control (Marek R et al., unpublished data). Computed tomography and histopathological assessments were conducted, with euthanasia at 180 weeks post-surgery. Between weeks 3–52, ZX00 screws fractured at the physis, with fragments migrating away from the growth plate. Physis defect size decreased after week 12, and no limb length discrepancies were detected at skeletal maturity. From week 104, Ti-implanted limbs were significantly shorter than ZX00-treated and control limbs. At the same time, Ti legs also exhibited axis deviation. Histological analysis showed no adverse effects on organ architecture or immune infiltration. Similar results were observed in another group study (Suljevic O et al., unpublished). Bone histology confirmed new bone formation without foreign body response or screw encapsulation. These findings align with other studies from our research group in recent years.

Most pediatric implants in use are screws or K-wires. While screws are already available on the market with CE certification, a K-wire made from magnesium has been developed for the first time. Based on this innovation, a clinical trial in children is planned for distal radius fractures. This research aims to advance the development of resorbable implants, fostering healthier solutions in pediatric orthopedic trauma care.

POSTER SECTION

Intraoperative Evaluation of Right Ventricular Mechanics in a Pressure-Overload Swine Model.

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Objectives: Assessment of right ventricular (RV) mechanical performance during open chest surgery is typically based on invasive methods and subjective evaluations. This study developed a porcine model of acute progressive RV pressure overload to evaluate hemodynamic changes and validate the 3D-video kinematic assessment of the Videocardiograph (VCG).

Methods: Seven healthy Landrace pigs were instrumented under fluoroscopic guidance with Swan-Ganz and RV conductance catheters. Following a median sternotomy, pulmonary artery banding (PB) was performed in two stages to induce minimal (PBmin) and maximal (PBmax) pressure overload. In a proof-of-concept experiment, different PB steps were performed to record both videos for the VCG and invasive pressure-volume assessments (PV-loop). Additionally, these videos were subjectively evaluated by five consultant surgeons, similar to clinical routine.

Results: PBmax significantly increased Pes from baseline (21.17±3.31mmHg vs 39.85±7.82mmHg, p=0.001) and led to RV dilation, reduced ejection fraction (52.80±10.36% vs 33.99±9.88%, p=0.012), and decreased myocardial efficiency. In the proof-of-concept experiment, visual evaluations were highly variable among the cardiac surgeons, resulting in only a moderate reliability of their assessments (ICC=0.59 for RV-function; ICC=0.60 for filling status). VCG-derived epicardial z-axis displacements, systolic timing, diastolic velocity and volume demonstrated excellent relationships with PV-loop data.

Conclusions: This study established a porcine model of progressive RV pressure overload with robust PV-loop assessment. VCG-derived epicardial kinematics reliably quantified RV mechanical activity and correlated with gold-standard hemodynamic measurements. This non-invasive, cost-effective method shows promise for early detection of acute RV dysfunction in the operating room and warrants further clinical investigation.

Paediatric Formulation Challenges for Enteral Feeding Tube Administration – Current Understanding and Future Directions.

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The complex interplay between drug formulation risk factors and inherent anatomical and physiological differences put paediatric population at higher risk for administration of medication via enteral feeding tubes (EFTS). Hence, understanding the critical attributes of dosage forms and the interplay between tube, administration, and formulation factors is crucial for developing and evaluating products intended for administration via EFTs in paediatric patients. By thoroughly examining these aspects, the industry can identify specific challenges and requirements, leading to more effective and tailored drug formulations that not only meet the unique needs of paediatric patients but also ensure optimal delivery and efficacy when administered through EFTs. Moreover, a comprehensive understanding of these factors can guide regulatory evaluations and quality assurance processes. However, current literature reveals significant gaps in knowledge regarding some of these factors. There are several neglected areas that require further exploration and deeper understanding. This systematic review provides current understanding of these factors and highlights the areas of more targeted research needed to address the gaps, optimize formulation strategies, and ensure that products are both effective and safe for paediatric use via EFTs.

Knowledge Translation in Pediatric Rehabilitation Technology: From Research to Practice.

Patrice L. (Tamar) Weiss[1,2], Naomi Gefem[2], Barbara Maser[3], Tal Krasovsky[1]

1 – University of Haifa; 2 – ALYN Hospital; 3 – McGill University

Knowledge Translation (KT) is the process of applying research evidence to clinical practice to improve healthcare accessibility, effectiveness, and accountability. In pediatric rehabilitation, KT is essential for integrating novel technologies that enhance function, participation, and quality of life for children with disabilities. Despite technological advancements, many rehabilitation innovations face barriers to clinical implementation. This presentation will explore KT using three successful examples: powered mobility, head support systems, and telerehabilitation. Technological solutions, from hardware to software-based interventions, hold promise for improving rehabilitation outcomes. However, traditional research methodologies (e.g., randomized clinical trials) may not be suitable for evaluating assistive technologies due to rapid innovation cycles and the need for personalized adaptation. As a result, many promising technologies struggle to reach widespread clinical adoption.

Examples of successful knowledge translation in pediatric rehabilitation include: (1) Powered Mobility for Young Children, (2) Head Support Systems for Improved Function and Comfort and (3) Telerehabilitation for Remote Therapy Access.

(1) Historically, powered wheelchairs were not funded for children under six, based on the belief that young children could not safely operate them. Occupational therapists used global research evidence to advocate for early powered mobility, demonstrating that even toddlers could learn safe wheelchair use. Through policy change and simulator-based training, powered mobility became more accessible, improving independence, participation, and self-confidence.

(2) Proper head support is essential for children with severe disabilities, aiding posture, breathing, swallowing, and communication. A startup company, Headovations, partnered with clinicians to develop an innovative headrest (Headaloft). Through clinical trials and user feedback, the design was refined for better adaptability and comfort. The success of this project illustrates how collaborative development and real-world testing drive adoption.

(3) Telerehabilitation, using videoconferencing for therapy, was rapidly adopted during COVID-19. It addressed geographic and accessibility barriers, particularly for children unable to attend in-person sessions. The success of telerehabilitation led to ongoing hybrid models, expanding healthcare access. Challenges included technology literacy, regulatory concerns, and therapist training, highlighting the need for structured implementation strategies.

In contrast, some technologies remain in the research phase due to cost, feasibility, or technological maturity: Brain-Computer Interfaces (BCI): Despite decades of research, BCI remains impractical for clinical use due to high costs, complexity, and inconsistent performance. Robotic Feeding Devices: While robotic arms have potential for independent feeding, they are expensive and lack funding support, leading to limited adoption.

Factors influencing the success of knowledge translation include early stakeholder involvement, user-centered design, funding availability, and real-world testing. Barriers to success include high costs, regulatory hurdles, lack of clinician training, and slow policy changes. Technologies that succeed in clinical adoption often follow a structured KT approach, integrating research, user feedback, and iterative design.

In summary, effective knowledge translation bridges the gap between research and clinical practice, ensuring that children with disabilities benefit from emerging technologies. Future efforts should enhance research-to-practice pathways, focus on early design partnerships, and optimize the timing of clinical adoption. By overcoming KT barriers, rehabilitation professionals can work with families to maximize participation and quality of life for children in need.

SensiVR: an Extended Reality (XR)-based Digital Therapeutic solution (DTx) for the hybrid care of children with fine motor function disorders, using Virtual Reality (VR) and hand tracking technology.

Katarzyna Koba[1]

1 – RoboKoba

Background: The problem of limited availability and accessibility for traditional hand therapy for children is significant at both European and global levels. The dyspraxia condition, which causes a child to perform less well than expected in daily activities for their age and appear to move clumsily, affects 5-6% of the paediatric population. To address this issue, there is an urgent need to shift from paternalistic and expensive hospital-based treatment to individualized, hybrid outpatient intervention in pediatric care understanding patients' requirements. SensiVR is a unique, innovative VR-based and AI-driven serious game in the form of a Sensory Virtual Room (SVR) that provides monitoring with a personalized and digital therapeutic (DTx) approach to patients in both clinical and community settings. SensiVR reduces health inequalities in children's fine motor function skills, focusing mainly on prevention of mental health and improvement of movement skills with neurodevelopmental disorders such as Developmental Coordination Disorder (DCD), also known as dyspraxia syndrome related to the Sensory Processing Disorders (SPDs).

Methodology: Patients with diagnosis of various motor impairments and healthy volunteers will be included in the study. The structure of the study involves validation of AI models and ML models allowing us to observe the physical effects of muscle tone on the other motor skills through real-time biofeedback data analytics, while hand immersive training aims to mimic natural gesture sequences. The intended application is to improve fine motor function skills using VR and hand tracking technology in a sensory feedback and gamified Virtual Environment (VE). We chose a comparison group in which 50% have a diagnosis of various motor impairments and 50% have no disorders.

Results: The results obtained will highlight how SensiVR could improve children's school performance, such as writing, reading or speech as well as social interaction and emotional balance. Additionally, planned clinical trials in different countries might be a crucial step in the more patient-oriented and effective diagnosis of neurodevelopmental disorders among children.

Conclusion: The project aims to show that SensiVR has enormous potential in paediatric somatosensory and neuromuscular rehabilitation approaches and underline the importance of as well as early intervention for a variety of neurodiverse disorders affecting children.

Quantitative motor developmental trajectory for preterm infants based on unobtrusive technology.

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Preterm birth leads to an increased risk of long-term consequences, with over 50% of children born <30 weeks facing motor, cognitive, and behavioural impairments [1]. Motor development is closely linked to neurodevelopmental outcomes, so early, longitudinal monitoring of motor development is key to timely identifying neurodevelopmental disorders [1]. Current identification of potential motor impairments is based on motor-milestones achievement and clinical examinations. The first have demonstrated poor specificity, the latter are long and expensive, require trained personnel, limiting assessments only to the high-risk children [2].

Recently, technology-based approaches have been proposed for the assessment of motor performance in preterm infants, toddlers and children, with the final aim of early identifying motor impairments through usable tests for a widespread application [3,4]. Typically, these solutions rely on 2D/3D video capture or wearable inertial sensors and resulted promising, highlighting quantitatively measurable differences between preterm and full-term peer motor performance [3-5]. However, these studies remain predominantly explorative and descriptive: the analysed quantitative variables are focused exclusively on motor aspects during specific tasks and at a specific age, lacking a longitudinal perspective and a unified clinical interpretable meaning, fundamental to understand how motor difficulties prime and evolve and for an effective use in the clinical context.

This work aims at monitoring and interpreting the motor developmental trajectory of preterm infants, by using a unified quantitative technology-based approach, with the final aim of understanding causal pathways and identifying early biomarkers of motor impairments.

Very preterm infants (< 32 weeks gestational age) have been recruited and evaluated from birth to 24 months corrected age. Times of assessment match the timing of clinical follow ups (term equivalent age, 3, 6, 12, 18, 24 months, T0, T3, T6, T12, T18, and T24); a convenient control group of full-term infants with no apparent risk of neurodevelopmental disorder was also included.

Participants were assessed on the following specific milestone motor functions:

- Newborn quantitative motor assessment: video-based recordings of spontaneous movements (T0 and T3).
- Infant (>4 months) quantitative motor assessment: sensor-based [5] assessment of motor performance (sitting posture, independent posture, independent gait) from T6 to T24, when present.

Chosen technologies guarantee usability and acceptance in clinical context. Kinematic data are extracted from videos at T0 and T3 using open pose estimation technology (DeepLabCut [6]) and directly from sensors from T6 to T24. Quantitative interpretable metrics of motor control performance were extracted from the kinematic data of each analyzed task (e.g., phase time durations and variability, multiscale entropy for motor complexity, recurrence quantification analysis for motor regularity, harmonic ratio for smoothness, Poincarè plots for short and long term variability [5]).

Preliminary results presented here are specific to the analysis of independent gait at T18 and T24 (n=51). Very preterm children exhibited less mature motor performance compared to peers born at term, characterized by lower stability (i.e., longer stance and double support phases) and higher variability, independently from the analysed age and walking experience. This variability did not indicate a structured exploration of more complex movements, as evidenced by lower smoothness and complexity in the frontal plane. The ongoing longitudinal data collection for both preterm and full-term participants will increase the sample size, the tasks analysed, and will provide a longitudinal analysis of preterm motor trajectory.

[1] A.J. Spittle, et al. 2016; [2] K. Cahill-Rowley, J. Rose, 2016; [3] C.C.T. Clark, et al 2021; [4] K. Raghuram, et al. 2021; [5] M.C. Bisi, M. et al. 2022; [6] A. Mathis, P. et al. 2018