

PATIENT PERSPECTIVES ON DATA SHARING



Patients Advisory Council (PAC)

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- EURORDIS Working Group collecting different patient views on issues surrounding registries, biobanking and –omics research
- Advise the RD-Connect Governing Board from the patient perspective



PAC Who's Who?

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Muriel Gevrey, French Charcot Marie Tooth Association



Joseph Irwin, Jennifer Trust for Spinal Muscular Atrophy



Julian Isla, Dravet Syndrome Foundation



Sigurdur Johannesson, Alternating Hemiplegia of Childhood Federation of Europe



Anna Kole, EURORDIS



Dorthe Lykke, European Federation of Hereditary Spastic Paraplegia



Francisco Monfort, European Alliance of patients with Atypical Hemolytic Uremic Syndrome



Kay Parkinson, Alstrom Syndrome UK



Marita Pohlschmidt, Muscular Dystrophy Campaign



Daniel Renault, Federation of European Associations of Patients affected by Renal Genetic Diseases



Françoise Rouault, French Muscular Dystrophy Association - Téléthon



Balthasar Schaap, European Federation of Neurological Associations/EuroAtaxia



Juliette Senecat, EURORDIS



Inge Schwersenz, Spinal Muscular Atrophy Europe



Chris Sotirelis, Spinal Muscular Atrophy Europe



Oliver Timmis, The Alkaptonuria Society



Mariek Van Meel, NephcEurope



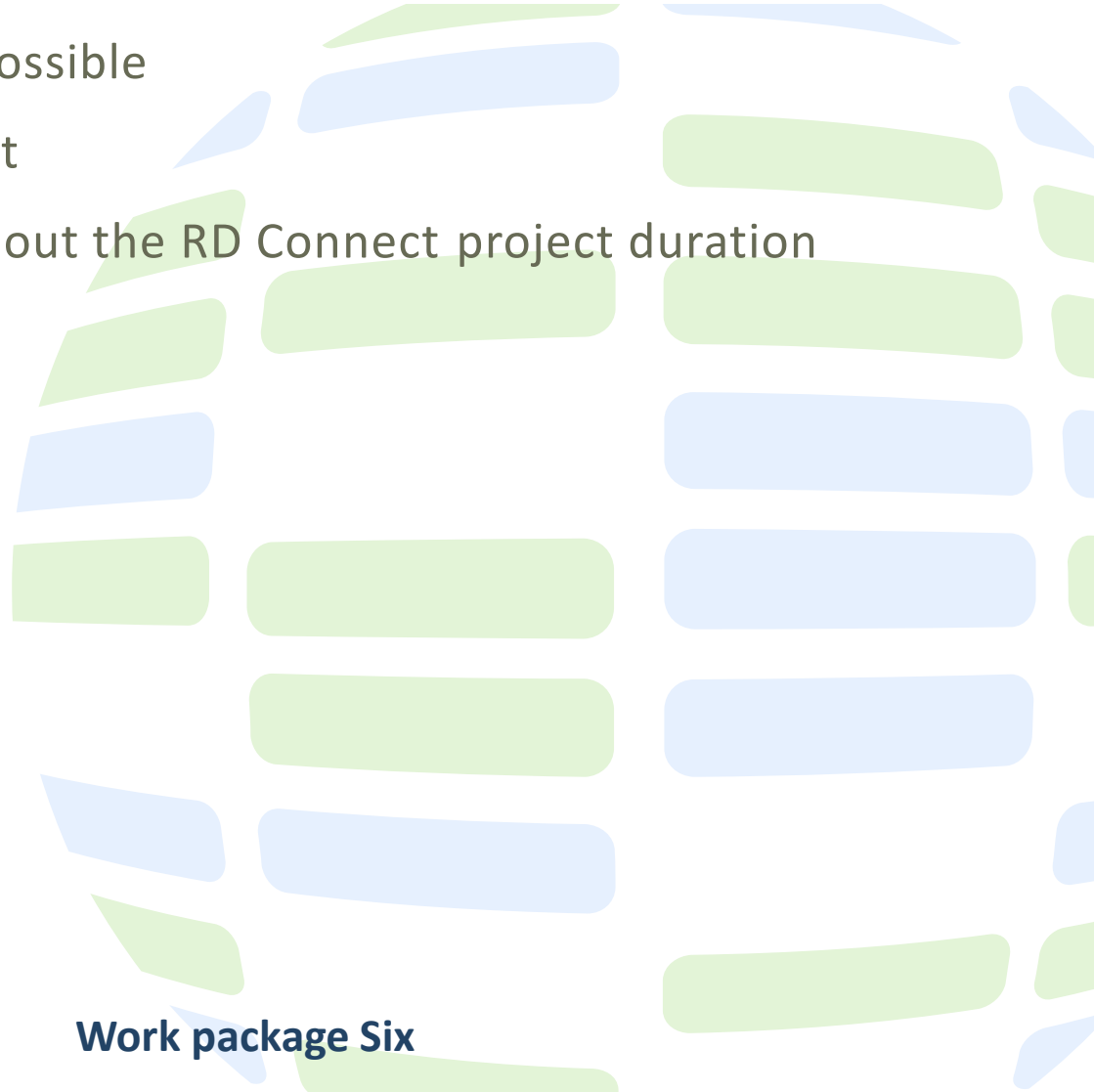
Elizabeth Vroom, United Parent Projects Muscular Dystrophy



Patient Perspective on Data Sharing

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- Building consensus where possible
- Highlighting areas where not
- Continuous process throughout the RD Connect project duration





1. Data Sharing as a Research Priority

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- Is it even a priority?
- Why?





1. Data Sharing is a research priority

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- RD patient community recognises that data sharing across national borders and stakeholders is necessary for high quality research particularly for RDs where data is scarce and patients are scattered
- RD patients have the most to gain in well characterizing the patient population through linking of data sources



2. Protection of Privacy

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- What are the limits?





2. Protection of patient privacy and confidentiality of data is critical

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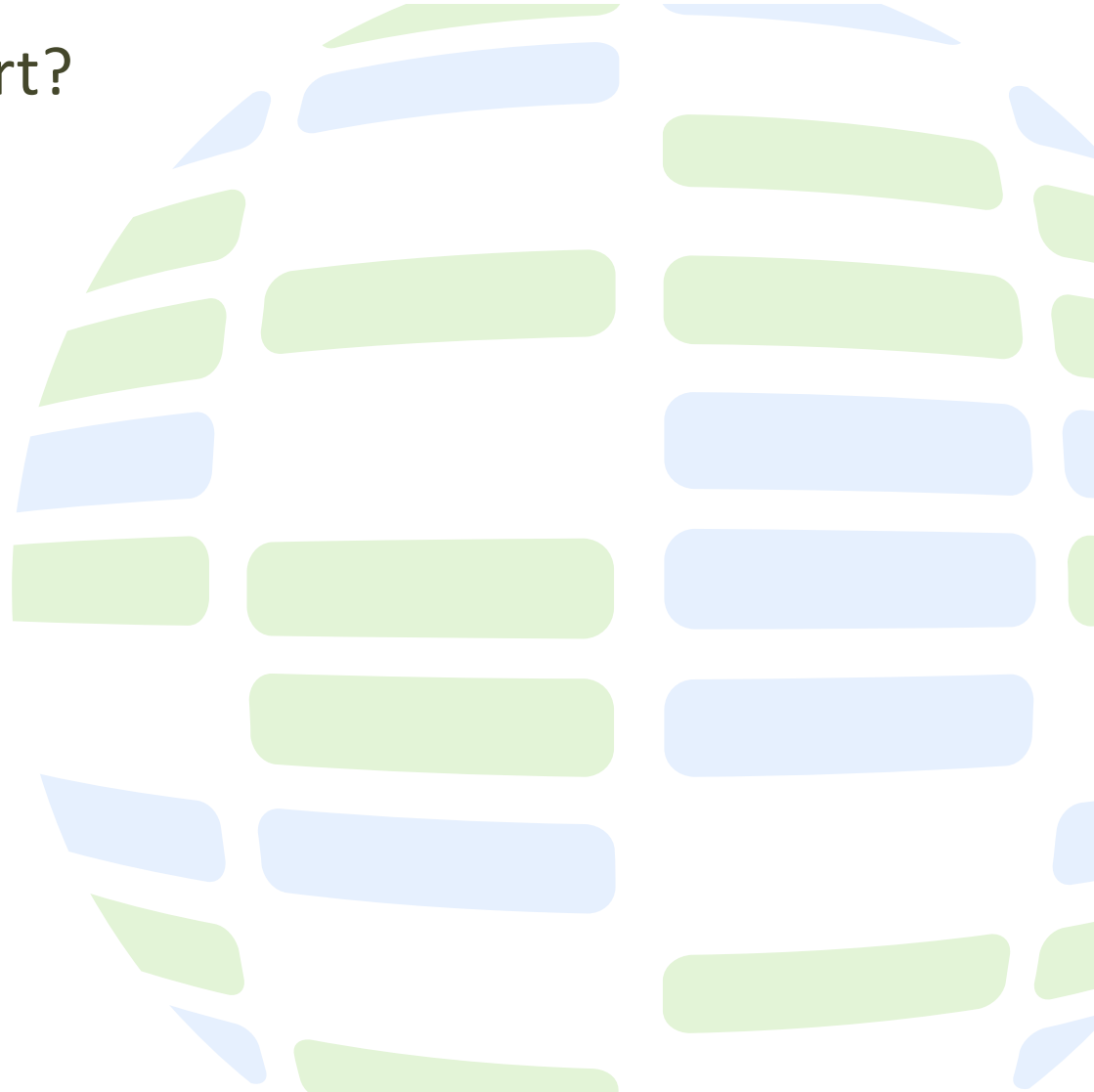
- Patients and the community at large understand that informational risks are involved in data sharing particularly when data are linked with a unique identifier
- Risks should be mediated through safeguards (such as ethical review, informed consent and IT solutions) while maintaining/respecting **reasonable** time frames
- The patient community requires additional capacity building on safeguards employed to best assess them



3. An EU Regulation on Data Sharing

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- Does this help or hurt?





3. A common regulatory framework can offer significant advantages

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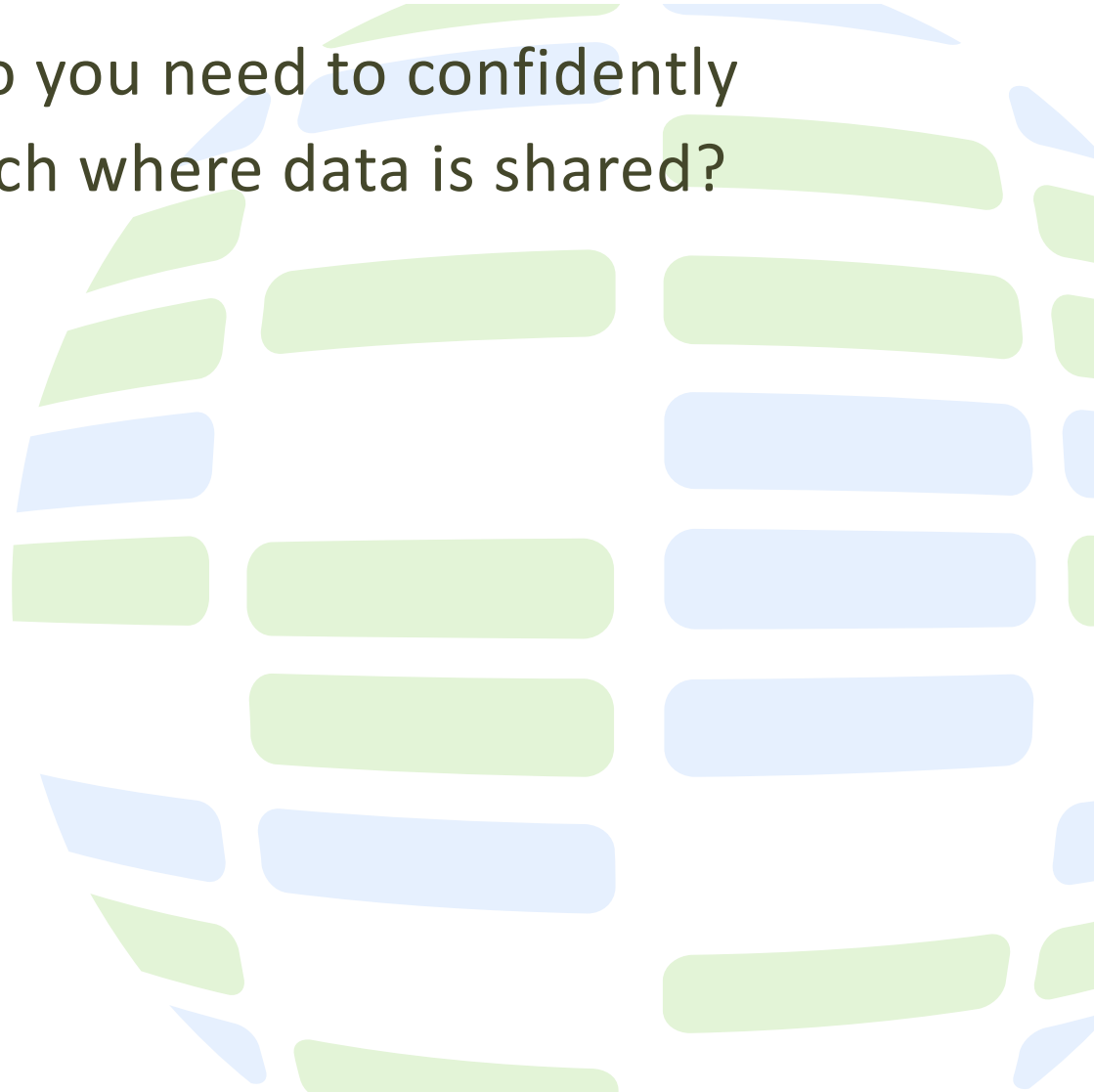
- A common data sharing regulatory framework **should** facilitate data sharing and harmonise protection of sensitive data
- The regulatory framework **should** include exceptions for health-related data that leave ample room for data sharing opportunities that propel scientific and medical progress
- Patients see the value in a separate health regulation or even a rare disease data regulation. An orphan data regulation?



4. Consent

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- What information do you need to confidently participate in research where data is shared?





4. Patients must consent to the sharing of their data

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- Consent models should provide research participants with the information they need to **feel confident** in participation
- Consent models may vary depending on the type of data sharing and must be balanced with communication with participants
- Within a consent framework use of patient data is highly dependent on an ethical review. The absence of a central European ethical review body will influence the most appropriate informed consent for transnational projects
- The creation of consent models and materials should include real patient representation to encourage overall participation



5. Governance

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- Do you want a say?
- How so?





5. The governance of data-sharing initiatives should be adaptive

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- Due to advances in regulations and technology, needs and expectations of all stakeholders are changing, including the patient community.
- The governance of data-sharing initiatives should reflect this need for adaptation
- Patient representatives should be equally represented in the governance of data sharing networks



6. Incentivising Data Sharing

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- How do you encourage everyone to play well in the sandbox?





6. Incentives for data-sharing should remain patient-centric

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- ❑ Publication policies
- ❑ Transparent collaboration with industry
- ❑ Data sharing culture change
- ❑ Should always keep patients interest at their core



7. Communication of Outcomes

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- Do you want to know?
- Who should tell you?
- How?





7. Outcomes of data sharing activities should be communicated

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- Communication of outcomes to the patient community and the public at large should occur in a **timely manner**
- Communication on individual results should be clearly anticipated in consent procedures