



EU Institutions

A changing landscape.

What is changing for rare diseases?

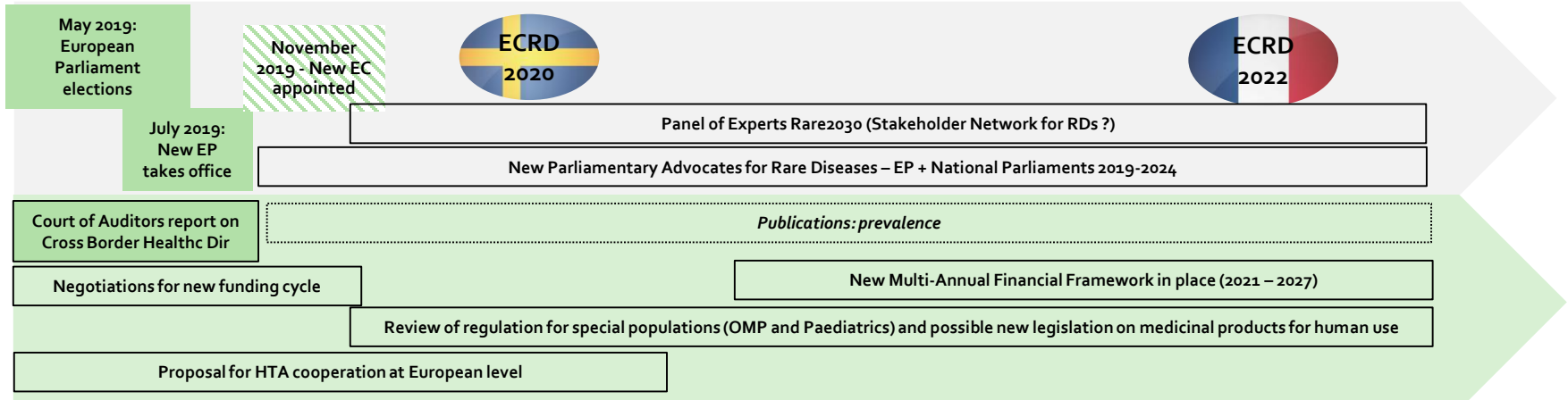
CEF meeting
8 November 2019
Brussels

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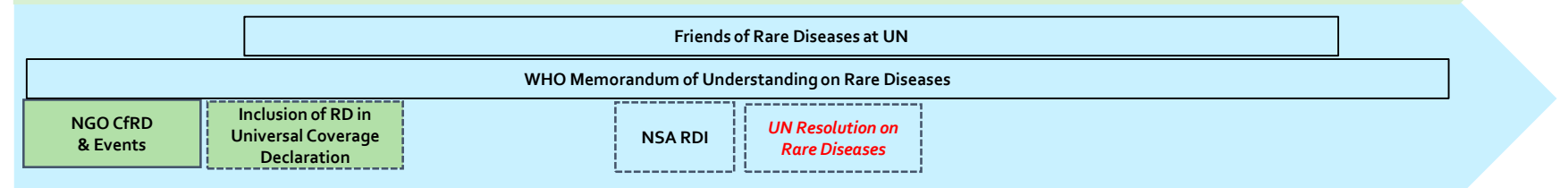




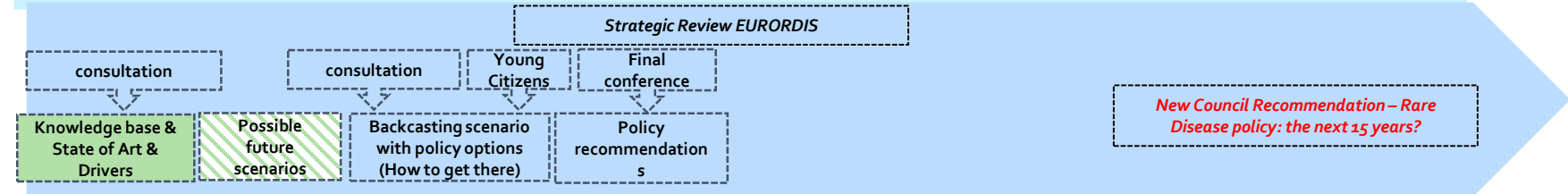
European policy level



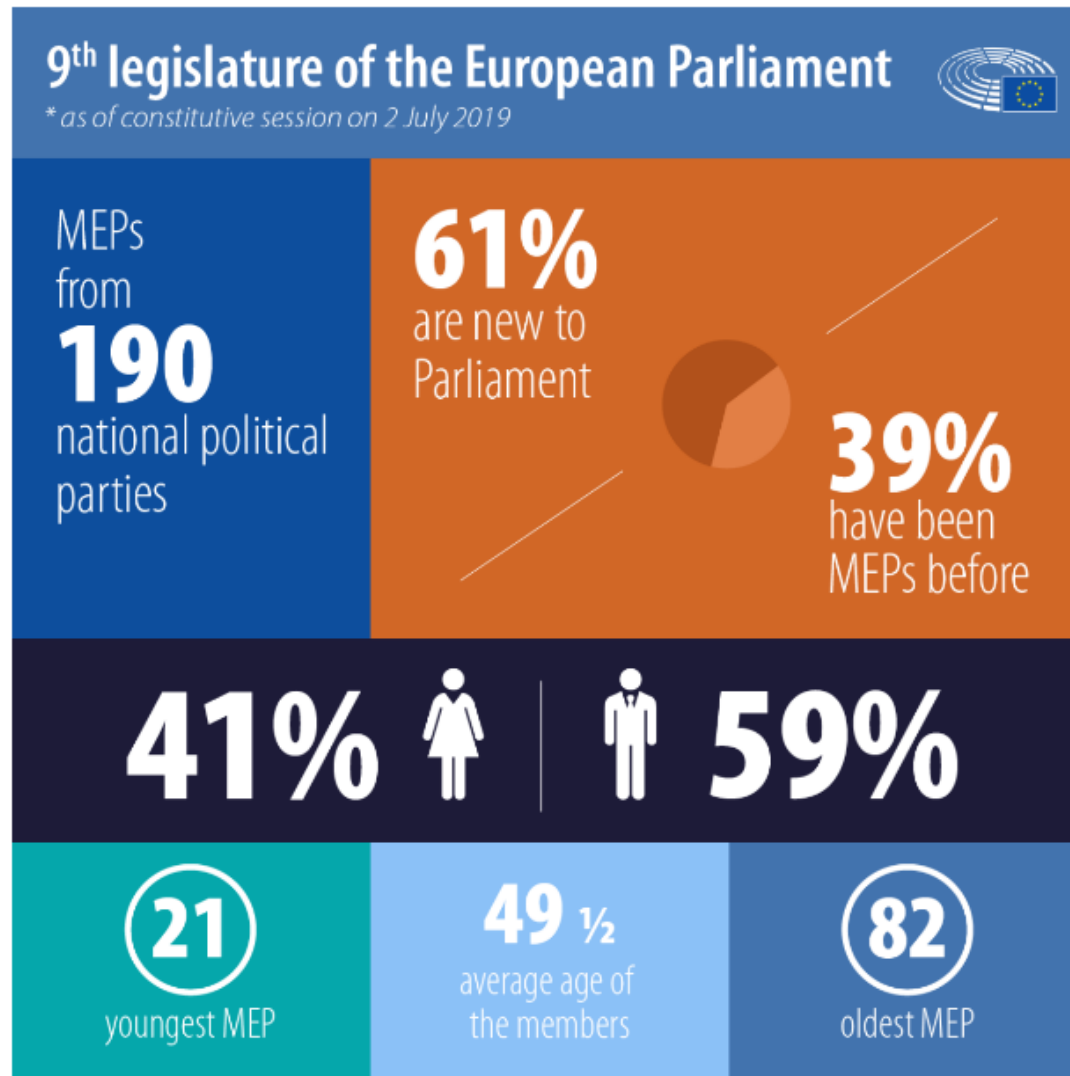
International policy level



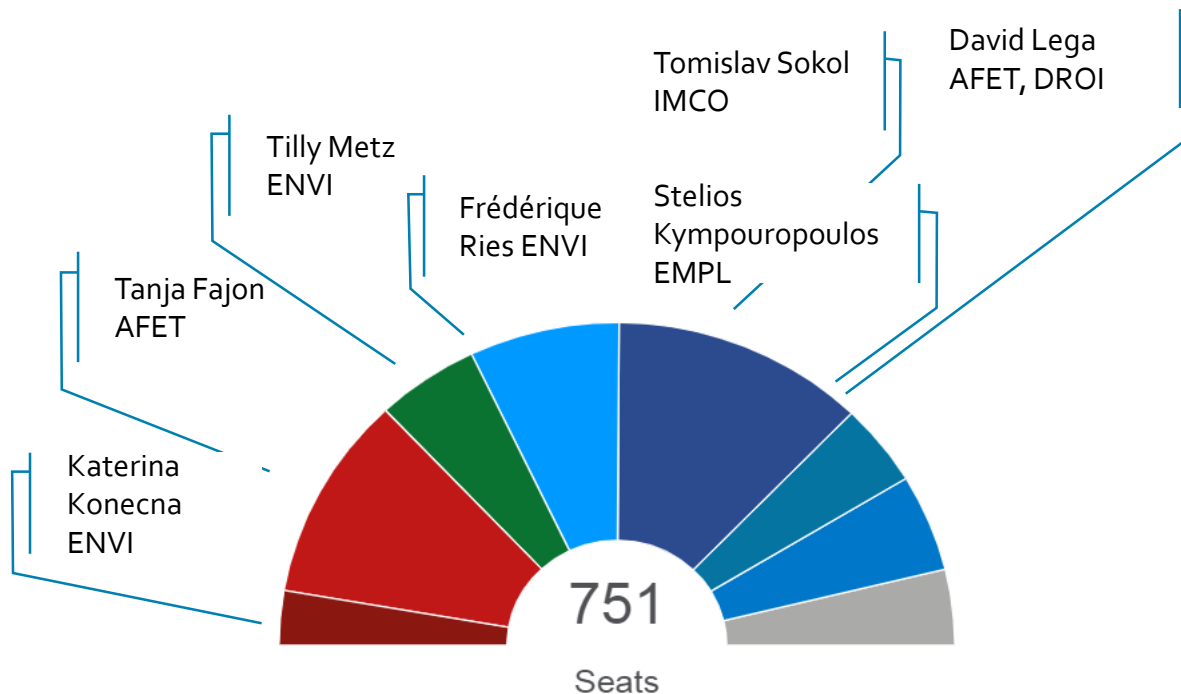
Foresight RARE 2030



A New European Parliament 2019-2024



Identifying RD champions



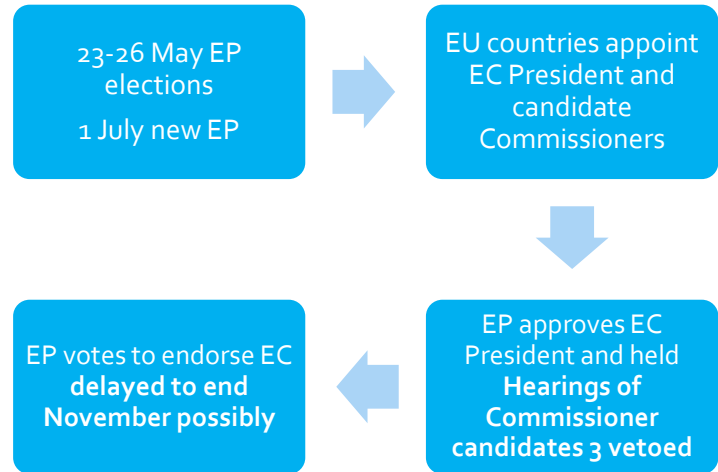
EPP Group of the European People's Party (Christian Democrats)	182	24.23%
S&D Group of the Progressive Alliance of Socialists and Democrats in the European Parliament	154	20.51%
Renew Europe Renew Europe group	108	14.38%
Greens/EFA Group of the Greens/European Free Alliance	74	9.85%
ID Identity and Democracy	73	9.72%
ECR European Conservatives and Reformists Group	62	8.26%
GUE/NGL Confederal Group of the European United Left - Nordic Green Left	41	5.46%
NI Non-attached Members	57	7.59%

- Mapping 112 MEPs so far (including 6 medical doctors, 3 former health ministers)
- 23 elected MEPs signed the Pledge₄RD during elections (8 new and 15 returning)

European Parliament

EP	Challenges	Opportunities
MEPs	<ul style="list-style-type: none">• Many old champions gone• Less EURORDIS connections with ENVI• Attention/Health monopoly: other groups vs EURORDIS• Other focus than RD• New MEPs and RD: what do they know, what can they do?	<ul style="list-style-type: none">• New champions to be found• New MEPs: doctors, medical, disabilities, ...• Some connections already made• Regulations on Orphan and Paediatric Medicines will be discussed and voted at the EP

The new EP approves the new European Commission



European Commission Candidates 2019-2024

 <p>Ursula von der Leyen (DE-EPP) Elected president 2019-2024</p>	 <p>Frans Timmermans (NL-S&D) Vice-president 2019-2024 EU commissioner for fundamental rights 2014-19</p>	 <p>Josep Borrell (SP-S&D) Vice-president 2019-2024 & High representative of the European Union</p>	 <p>Margrethe Vestager (DK-Renew) Vice-president 2019-2024 EU commissioner for Competition 2014-19</p>
 <p>Johannes Hahn (AT-EPP) EU commissioner for neighbourhood policy and enlargement negotiations 2014-19</p>	 <p>Kadri Simson (EE-Renew)</p>	 <p>Paolo Gentiloni Silveri (IT-S&D)</p>	 <p>Elisa Ferreira (PT-S&D)</p>
 <p>Didier Reynders (BE-Renew)</p>	 <p>Jutta Urpilainen (FI-S&D)</p>	 <p>Valdis Dombrovskis (LV-EPP) EU commissioner for euro and social dialogue 2014-19</p>	 <p>Dan Nica and Rovana Plumb (RO-S&D)</p>
 <p>Marlya Gabriel (BG-EPP) EU commissioner for digital economy and society 2014-19</p>	 <p>Sylvie Goulard (FR-Renew)</p>	 <p>Virginijus Sinkevičius (LT-Greens/EFA)</p>	 <p>Marek Šefčovič (SK-S&D) Commissioner's vice-president in charge of the energy union 2014-19</p>
 <p>Stella Kyriakides (CY-EPP)</p>	 <p>Margaritis Schinas (GR-EPP) Spokesperson of the EU commission 2014-19</p>	 <p>Nicolas Schmit (LU-S&D)</p>	 <p>Janez Lenarčič (SI-Renew)</p>
 <p>Dubravka Šuica (HR-EPP)</p>	 <p>László Trócsányi (HU-EPP*)</p>	 <p>Helena Dalli (MT-S&D)</p>	 <p>Ylva Johansson (SE-S&D)</p>
 <p>Věra Jourová (CZ-Renew) EU commissioner for justice, consumers and gender equality 2014-19</p>	 <p>Phil Hogan (IE-EPP) EU commissioner for agriculture and rural development 2014-19</p>	 <p>Janusz Wojciechowski (PL-ERC)</p>	 <p>The UK has officially confirmed that it will not nominate a European Commissioner candidate.</p>



A new European Commission

Stella Kyriakidou

Commissioner for Health

(endorsed)

Ursula von den Leyen

President of the European Commission

→ **Hearing before the EP**

→ **Written and Oral Questions by MEPs**

→ **Mission Letter to Stella Kyriakides**



EURORDIS inputs to MEPs and Stella K. before Hearing



European Commission

EC	Challenges	Opportunities
Ursula von der Leyen	<ul style="list-style-type: none"> • Affordability of and access to medicines • Minimum income • AMR • Cancer plan 	<ul style="list-style-type: none"> • Affordability of and access to medicines • Cancer plan
Stella Kyriakides	<ul style="list-style-type: none"> • Focus on cancer • Focus on climate, environment, food safety • RD not specifically addressed (except ERNs) 	<ul style="list-style-type: none"> • Focus on cancer -> rare cancers? • Health in all policies • Focus on patient empowerment • Aims for further EU collaboration • Focus on digital health
DG SANTE	<ul style="list-style-type: none"> • OMP/PAD evaluation • Perception of RD job done 	<ul style="list-style-type: none"> • OMP/PAD evaluation • Focus on ERNs • Joint work on health research • Framework RD by 2023

EU Council Presidencies 2019-2023



FRANCE

- First discussion at MoH on Presidency priorities
- Fostering meeting with CZ Republic

CZECH REP.

- Advanced work on EU Presidency priorities
- Possible inclusion of RDs in health priorities *if* supported by previous Presidency (FR)

EU Council

EU Council	Challenges	Opportunities
	<ul style="list-style-type: none">• HTA legislation• Cancer plan• Brexit• Budget	<ul style="list-style-type: none">• HTA legislation• Cancer plan• Future EU presidencies

European Court of Auditors



Review of the Cross-border healthcare Directive by the ECA – JUNE 2019

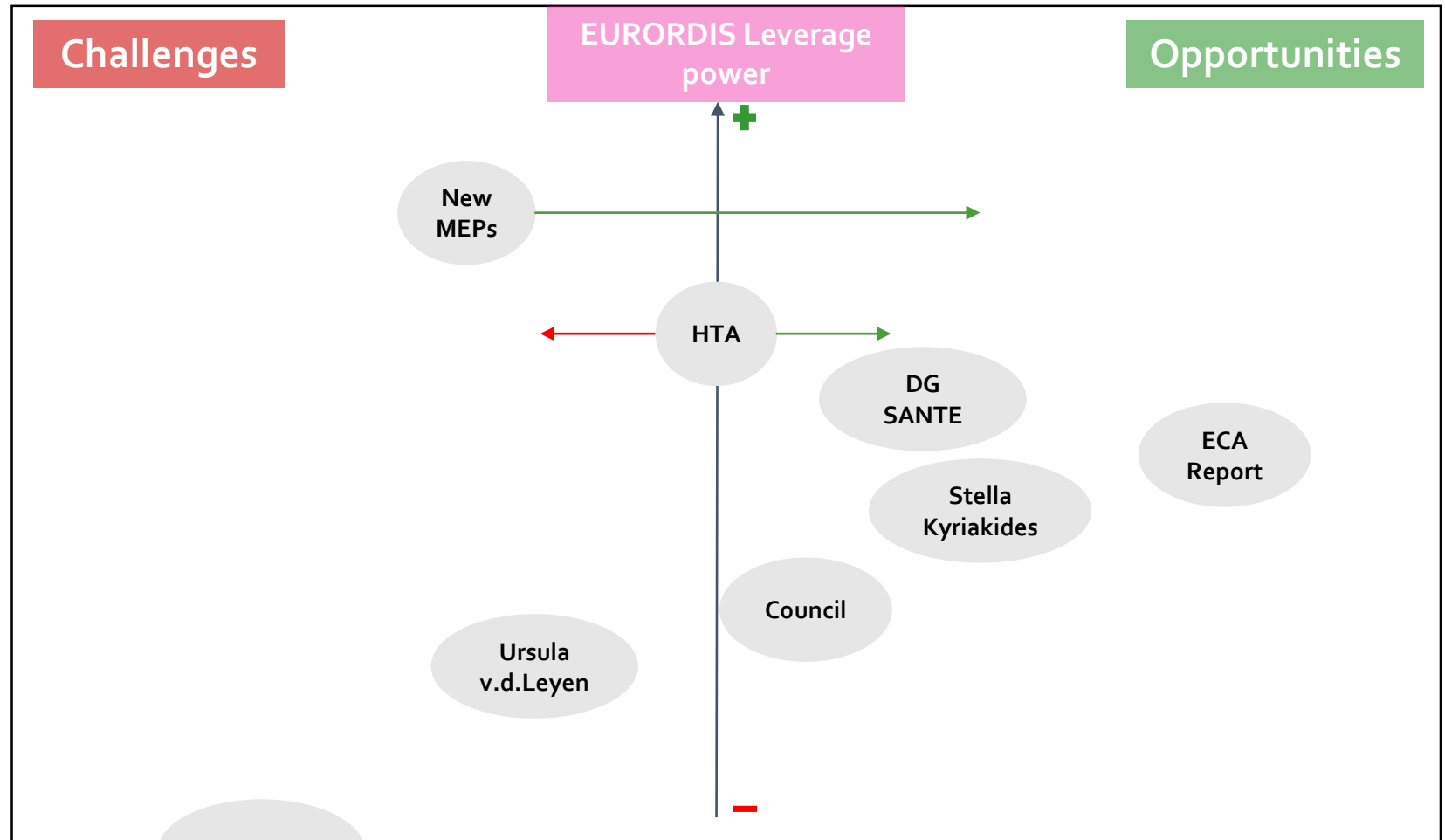
The Commission should:

- (a) by **2023** - **assess the results of the rare disease strategy** (including the role of ERNs) and decide whether this strategy needs to be **updated, adapted or replaced**;
- (b) by **2020** - in consultation with MS set out ways forward to address the challenges faced by the ERNs (incl. integration of ERNs into national healthcare systems, and patients' registries);
- (c) by **2022** - work towards a simpler structure for any future EU funding to the ERNs and reduce their administrative burden.

European Court of Auditors (ECA)

ECA	Challenges	Opportunities
	<ul style="list-style-type: none">• Not binding on EU legislator	<ul style="list-style-type: none">• Official backing of need to review the EU RD strategy;• Support to sustainability of ERNs• Accepted by EC• Backed by Council of Ministers

Conclusion





Questions?

Comments?

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Meeting with DG SANTE Dir. General & team

1/ Policy framework on rare diseases beyond ERN & OMP regulation

- Follow-up to the European Court of Auditors (ECA) Report; update on Rare2030 Foresight study (co-funded by the EU Pilot Projects and Prep. Actions Programme)

2/ EC commitments on improving the implementation of CBHC Directive

- With specific regard to ERNs and their sustainability - MFF 2021-2027 & follow up to ECA report

3/ State of play on access to therapies for people living with rare diseases –

- Progresses on proposal for EU cooperation on HTA and EC plans to support the proposal through the legislative process - EURORDIS proposals

4/ Challenges in accessibility across Europe, aggravated situation for recent gene & cell therapies

5/ Evaluation of regulatory incentives for special populations (OMPs, paediatrics)