What patients and caregivers want to happen now: priorities for action

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PML – Balancing risks and benefits. The patients' view
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Call for action – general issues addressed to regulators

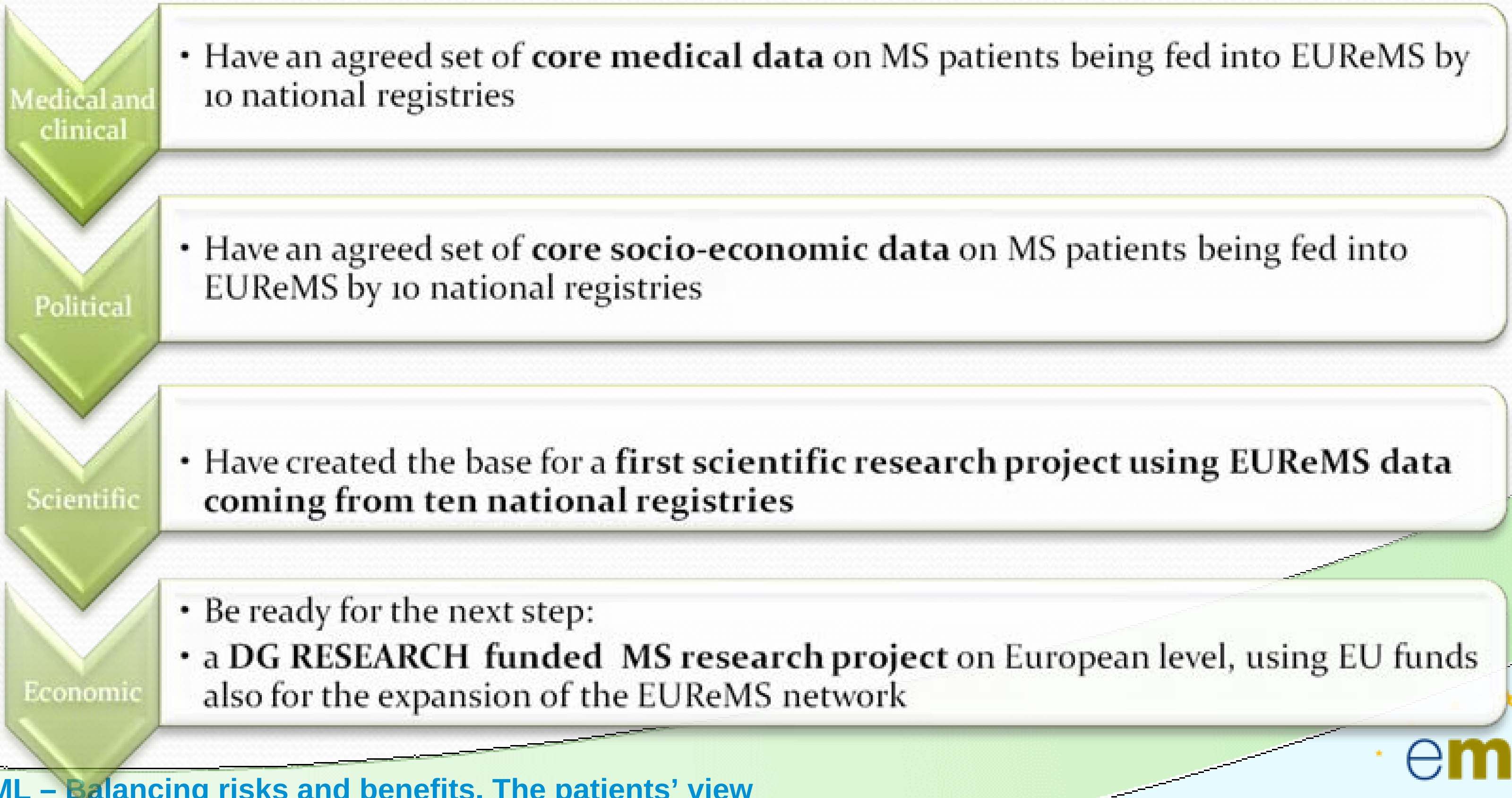
- *Role of patients & care givers as final voice in risk-benefit assessments of new medicines needs to be strengthened further (CHMP representation?)*
- *More frequent interaction between patient groups, health professionals and regulators is needed on benefit-risk discussion and research (good example: EMA survey & workshop in 2009 on ways to improve the EMA information on benefit & risk of medicines)*
- *Better use of dissemination of vital benefit - risk information to the individuel patient via patient organisations*

Call for action – specifically on PML

- *Clarification to Tysabri users of the capacity & limitations of blood tests on JCV antibodies as risk indicator*
- *More studies on the – apparently decreasing – risk of developing PML after 3 years of Tysabri use & the 2 years rule*
- *Public private partnership in research on effective anti JC viral therapy (new IMI call is out now…)*
- *Internet based networking of PML patients & care givers to be supported / facilitated (by EMA /FDA/ or MSIF?) and/or*
- *Central database on PML cases to be made available to patients & families once a PML diagnosis is made*

EU & Industry co-funded project European Register for Multiple Sclerosis (EUReMS) 1, 5 Million Euro 2011-2013

- By mid 2014, EUReMS will ...



Medical and clinical

- Have an agreed set of **core medical data** on MS patients being fed into EUReMS by 10 national registries

Political

- Have an agreed set of **core socio-economic data** on MS patients being fed into EUReMS by 10 national registries

Scientific

- Have created the base for a **first scientific research project using EUReMS data coming from ten national registries**

Economic

- Be ready for the next step:
- a **DG RESEARCH funded MS research project** on European level, using EU funds also for the expansion of the EUReMS network

Thank you!

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