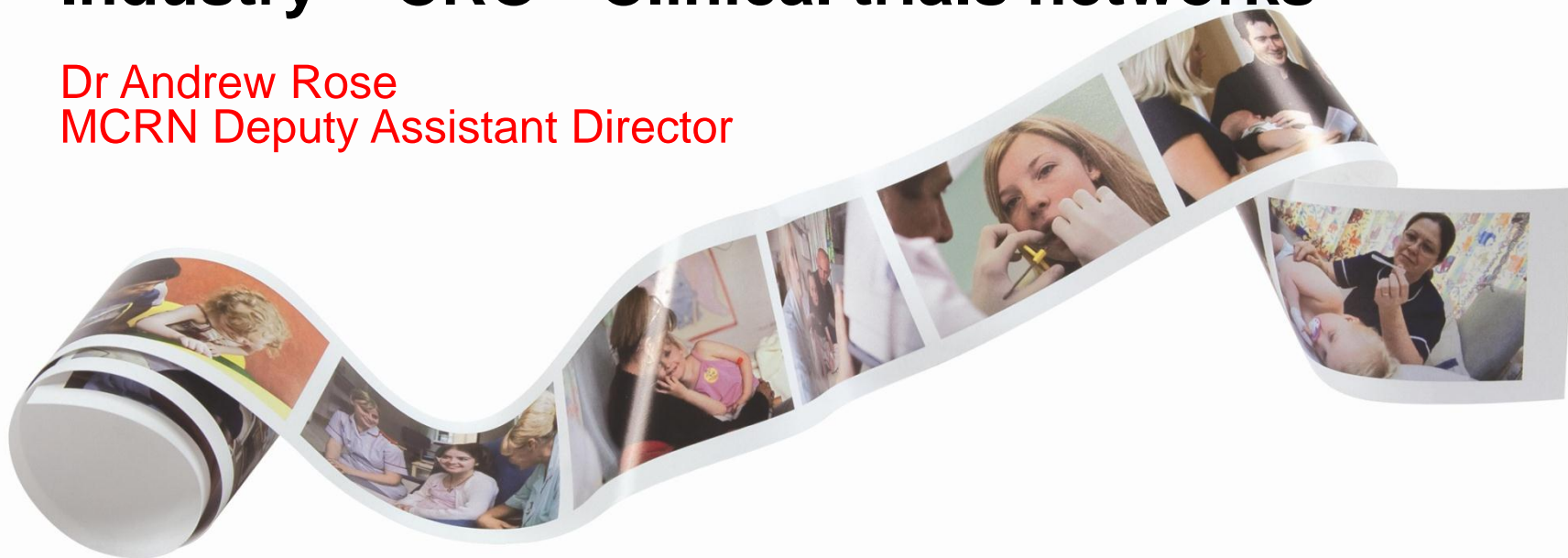


The interface: Industry – CRO - Clinical trials networks

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Outline

- Network services
 - Advice
 - Feasibility
 - Setup and recruitment
- Network models
- Strengths and weaknesses
- Challenges
- Conclusions

Advice

- Scope
 - Protocols and programmes
 - EU Paediatric Regulation
- Network organisation
 - Specialty Groups
- Considerations/models
 - Perspective dependent on Network (Disease-specific, National...)
 - Early engagement between sponsor/CRO and Network is key
 - Charging? (Level of input from Network, link to experts...)
 - Patient involvement
 - What role does Enpr-EMA have in facilitating links?



Clinical Studies Groups (CSGs)

NHS
*National Institute for
Health Research*

Clinical Research Network

Allergy, Infection and Immunity (BPAIIG)
Anaesthesia, Pain, Intensive Care and Cardiology
Cleft and Craniofacial Anomalies
Diabetes and Endocrinology (BSPED)
Gastroenterology, Hepatology and Nutrition (BSPGHAN)
General Paediatrics (including Dermatology) (BAGP)
Inherited Metabolic Disorders (UK LSD)
Methodology
Neonatal (Action Medical Research)
Nephrology (BAPN)
Neurosciences
Pain and Palliative Care (Louis Dundas Development Fund)
Pharmacy and Pharmacology
Respiratory and Cystic Fibrosis
Rheumatology (Arthritis Research UK)

Dr Saul Faust
Dr Mark Peters
Ms Rona Slater
Prof Timothy Barrett
Dr Nick Croft
Dr Colin Powell
Dr Chris Hendriks
Prof Ruth Gilbert
Dr Mark Turner
Prof Moin Saleem
Dr Timothy Martland
New
Prof James McElnay
Dr Paul Seddon
Prof Michael Beresford

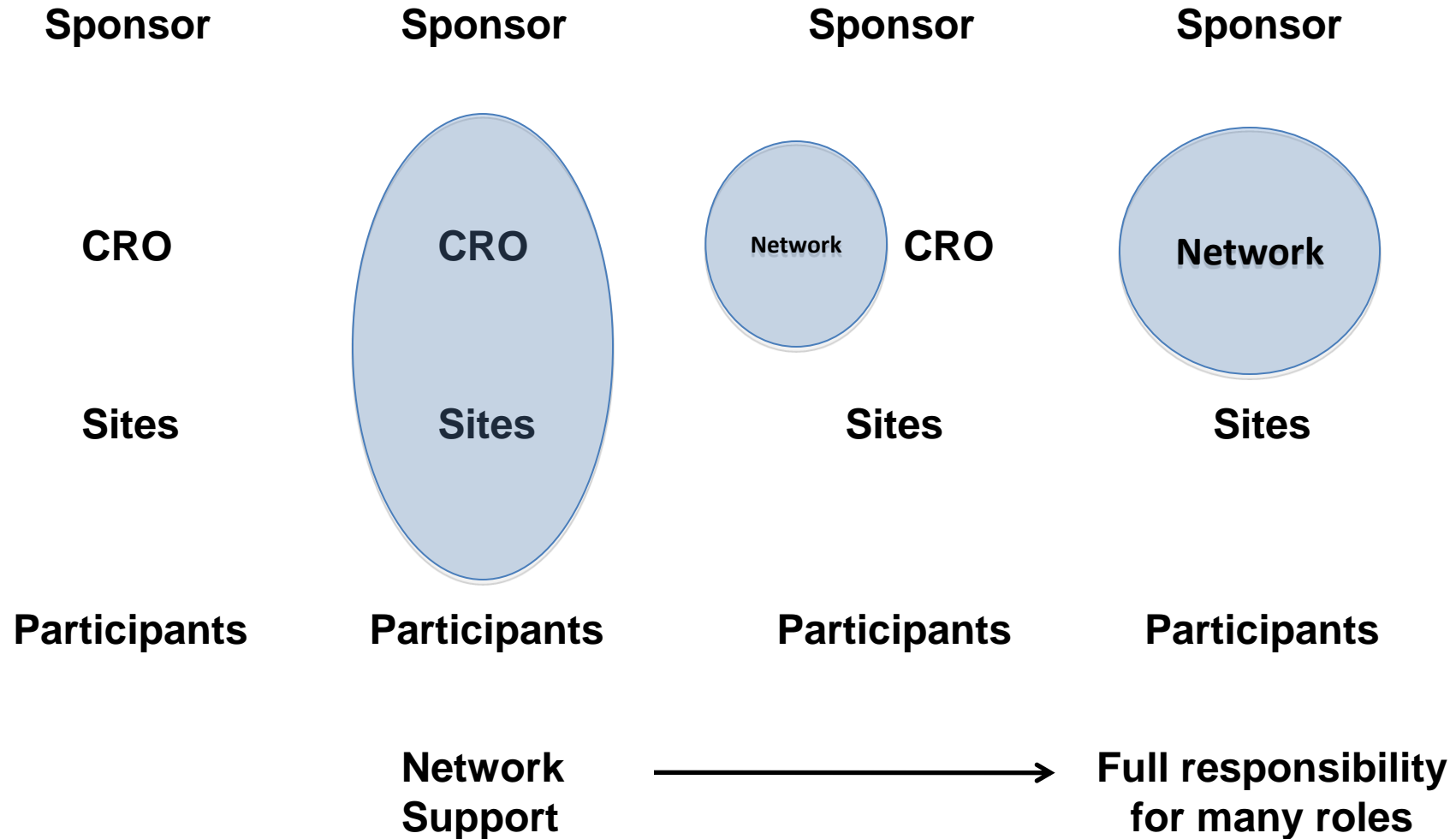
Feasibility

- Scope
 - Top-level review (Is the study going to work in particular country...)
 - Site identification
 - Support for sponsors/CROs/investigators when sites validated
 - Check feasibility/resources/costs
- Network organisation
 - Regional structure of National Networks
- Considerations/models
 - What do our customers want? Are we duplicating activities of CROs?
 - Delegation of activities to Networks (acting like CRO)/supporting CROs
 - Charging? (Level of service/information that Network can provide, loss-leader, link to experts...)
 - Enpr-EMA role?

Setup and Recruitment

- Scope
 - So study can open and recruit successfully, need to facilitate:
 - Reg approvals, contracts, costs, resourcing, planning, training
 - Data monitoring
- Network organisation
 - Staff structure to facilitate delivery/monitoring (hands-on or direction)
- Considerations/models
 - Resources/staff availability often key (link back to feasibility)
 - Charging models - ensuring funds flow back to right place
 - Delegation of activities to Networks (acting like CRO)/supporting CROs
 - Monitoring to standards required?

Network models



Network strengths and weaknesses

- Strengths
 - Can be very effective at supporting activities
 - Provision of advice
 - Feasibility
 - Setup and Recruitment
 - Very effective at developing research infrastructure and expertise
- Weaknesses
 - Can have limited scope
 - Variation
 - In what they provide
 - In the enthusiasm of members
 - Voluntary / good will
 - Limited funding
 - Competition with CROs (real or perceived)

Challenges for Networks

- Investigators
 - Networks do not (always?) employ all investigators
 - Some investigators need to develop understanding of:
 - What is needed for industry studies
 - Benefits of a Marketing Authorization
 - Other factors
 - Culture of publicly-funded pragmatic trials (mainly post-marketing)
 - Industry priorities not always same as clinical priorities

Challenges for Networks

- Study design
 - Some poorly designed studies – complexity
- Capacity
 - Networks/sites/units/investigators
- Barriers outside the control of Networks
 - Health care systems
 - hospital management etc
 - Ethics etc
 - Situation getting better, but some things cannot be influenced by Networks...

Conclusions

- Networks want to deliver for sponsors and CROs
- Different models are in operation across Networks
- Early engagement, collaboration and communication are key
- How can we all work with Enpr-EMA to overcome the challenges that we experience?



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Health Research*

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