



An ELN-based MDS clinical trial coordinating office – on behalf of the German and French MDS groups

Sonya Faber, Uwe Platbecker, Pierre Fenaux

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GMIHO ist Sponsor und Serviceplattform für klinische Forschung in der Hämatologie und medizinischen Onkologie.



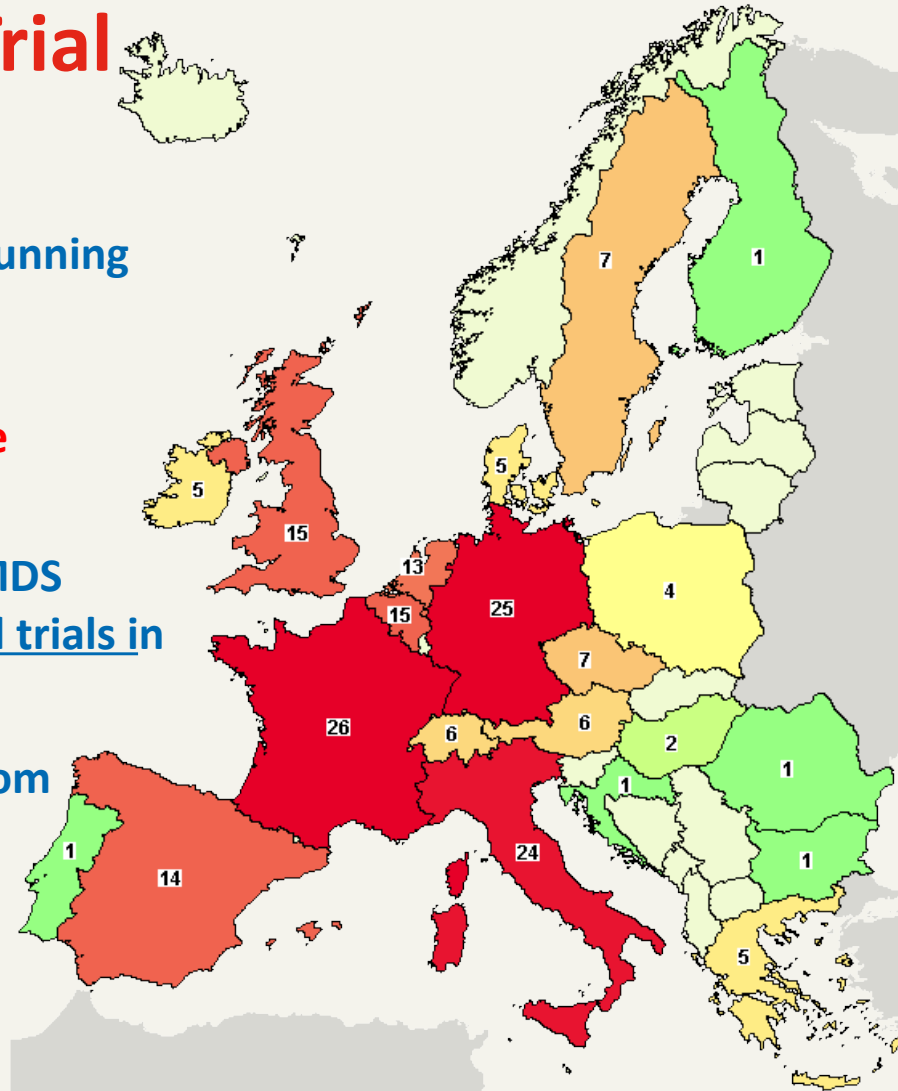
Current MDS Clinical Trial Landscape in Europe

Multiple MDS clinical trials are currently running across the EU

Of 389 worldwide open trials with known status, 25 are in Germany and 26 in France

Both the Groupe Francophone des Myélodysplasies (GFM) and the German MDS study group (GMDS-SG) sponsor 14 clinical trials in MDS

GMIHO (Dresden, Germany) originating from the DGHO is a specialist “PI Network” offering scientific expertise for efficient Sponsorship of IIT clinical trials. Sponsors 2 clinical trial in MDS





Trends in MDS

1. MDS research is becoming more international
2. Market Data reveals an upcoming need for more clinical trials in MDS
3. Sharp drop in clinical trials in the EU

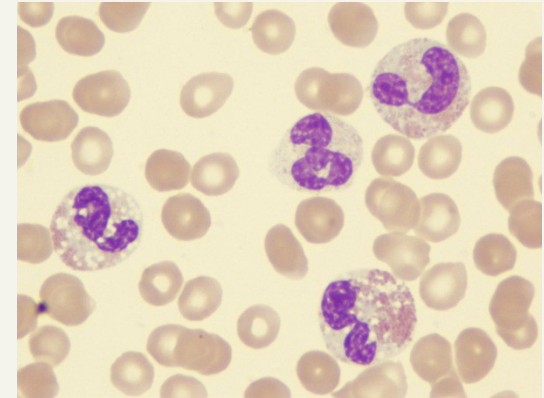


Over the next 5-7 years new medications in MDS will come into clinical testing, **international clinical trials** will be necessary

Conclusion:

MDS is -

- A Rare disease
- Has a strong pipeline
- Presents with increasing diversity complexity (e.g. mutations)



Therefore: In order to facilitate research, accelerate translation and optimize trial recruitment in MDS research in an ideal time frame, a *coordinated collaboration* and *partnership* between scientific study groups in Europe has been set-up



ELN MDS Studies Coordination Office

Sonya Faber PhD, MBA, Head of Clinical and Business Operations

An ELN platform -

- Allows extension of partnership by intensifying clinical trial exchange in the EU
- Allows both oversight and collaboration in clinical trials under the umbrella of the ELN

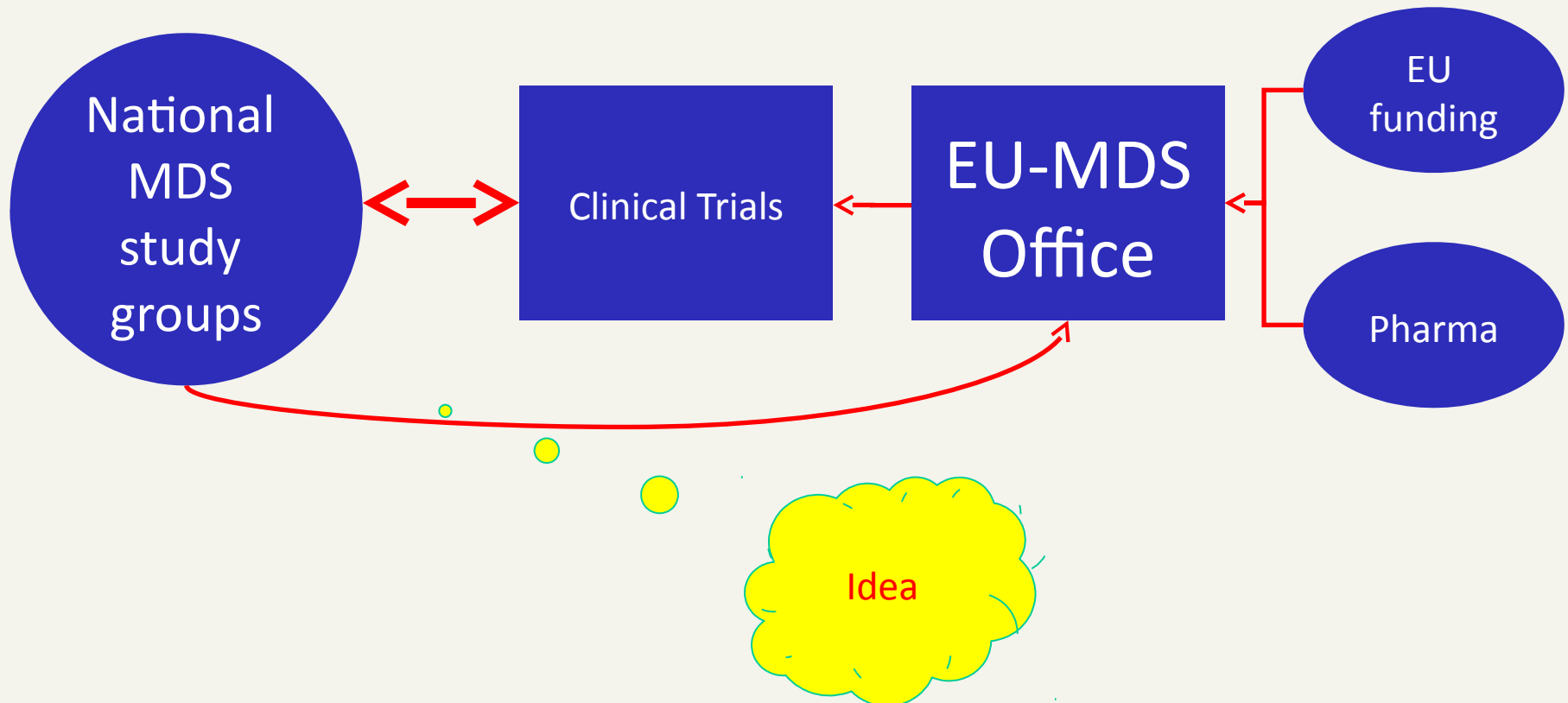
Primary Goals -

- Accelerate and Support MDS Research and Translation
- Prevent trial duplication
- Offer a focal point for trial design and consultation between major European MDS groups





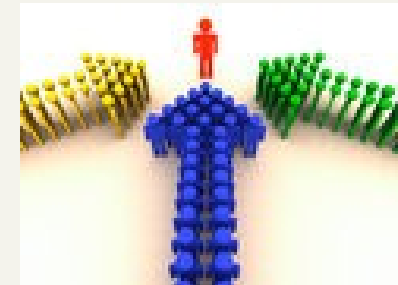
ELN MDS Studies Coordination Office





Advantages of an ELN MDS Studies Coordination Office

- Improved quality of clinical trials, especially for their management and data quality -> increased clinical relevance
- Rapid, efficient and cost-effective negotiations and agreement
- Rapid Patient recruitment
- Managed and standardized approach to ethical and regulatory approvals
- **Single point of contact** for Cross-European coordination between the pharma industry and national MDS Groups





EMSCO: MDS Studies Coordination Office

Phase 1:

An Office has been set-up located in Dresden and administered by the GMIHO in Berlin



Coordinator , on behalf of the
GMDS-SG and GFM : Uwe
Platzbecker



Dr. Sonya Faber is the Head
of Business Development





EMSCO: MDS Studies Coordination Office

Phase 2 (2013):

1. Request funding from Pharma to make EMSCO financially independent



www.emsco.eu

2. Website, logo



3. Set-up a common trial (GFM/GMDS-SG) sharing biostatistician, possibly CRAs, data collection and management with the goal to identify hurdles and practical problems (e.g. submission to IRB and national authorities, insurance, central randomization, monitoring etc.)

Phase 3 (2013/2014/2015):



Services – Conferences and Publications

EMSCO will implement:

- Conference organization, strategy-development, Kick-off meeting organization
- Coordination and conceptualization of common scientific publications, white papers and grants in MDS

Services – Trial Documents and Web Portal

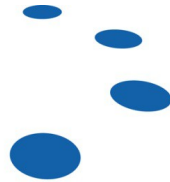
EMSCO will implement:

- Standardized Clinical Trial Documents and SOPs for MDS trials
- Web Portal
- Networking and Integration of Other Groups (send us your links)



EMSCO

MYELODYSPLASTIC
SYNDROMES



Thanks to:
GMDS-SG (Uwe
Platzbecker)
GFM (Pierre Fenaux)

Thank you very much
Merci!

Contact: Dr. Sonya Faber Phd, MBA
Head of Business and Clinical Operations
Tel: +49-351-25933-283
Fax: +49-351-25933-111
Mail: sonya.faber@GMIHO.de



Please send us your links!