



FIRALIS GROUP
Biomarker Development & Personalized Medicine

Prof. Hüseyin FIRAT, President & CEO
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European Parliament - Policy Department for Budgetary Affairs

Workshop on mid-term revision of the Financial Regulation :
Improvement of direct management

11 July 2016 / Brussels

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Group overview



Created in 2008

Domain: Biomarkers-based *In Vitro* Diagnostic (IVD) tools for “Precision Medicine”

Fully integrated business model:

>1600sqm of Shared platform for Service, R&D and Industrial activities


Proprietary products for 3 high impact pathologies

- Heart Failure
- Alzheimer’s Disease
- Rheumatoid Arthritis

Four acquisitions since the inception


About 70 people located in Paris, Strasbourg and Huningue / FRANCE

Key managers FIRALIS




CEO
Hüseyin Fırat

- Pediatrician, associate professor in Paris University hospitals
- PhD at Pasteur Institut, responsible of the Immunology lab at Génethon
- Head of worldwide biomarker sections at Novartis
- Founder of Firalis S.A.S
- CEO and President of Firalis and 4 affiliates



CEO Paris Affiliates
François Vallet

- "Ecole Polytechnique de Saclay", PhD in fundamental Physics at CEA
- CEO of Genewave, Theravectys, Vaxon-Biotech, Mablife & Mitricares



Firalis Group Histogram & Staff

Year	Staff Count
2009	5
2010	10
2011	13
2012	21
2013	30
2014	37
2015	60
2016	68

Business Advisor
Jörg Staeheli

Board of Directors
Pr. Alain Goezmann
Bernard Daugeras
Pr. Olivier Danos
Dr. Gilles Feutren
Jean-François Rax

Scientific Advisory Board
Pr. Dan Atar
Dr. Daniel WAGNER
Pr. Bruno Dubois
Pr. Serge Gauthier
Pr. Jean-François Démonet

Chief Medical Officer
Gilles Feutren

Regulatory Affairs and IP Officer
Béatrice Molac

Chief Business Officer
Tony Yaacoub

Chief Scientific Officer
Saliha Moussaoui

Chief Technical Officer
Xavier Preville

Patent attorney at Sando
Group Head of Pharma Patents Transplantation at

Business development at Fournier, Sanofi and Actelion biopharmaceuticals

PhD, INSERM, Boston MGH
Head of Neurodegeneration department at Aventis and Novartis

Chief scientist in Gentical
Founder of Procerivix® vaccine
Leader of preclinical activities at Transgene

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Selected European Grants obtained FIRALIS

FRAMEWORKS	Project	Start	Funding	Coaching	Focus	Overall
IMI	SAFE-T	2009	75 + 20%			6/10
	BT-Cure	2013				
FP-7	Imagint	2011	75 + 60%			8/10
	Mitocare	2011				
	Fibrotarget	2013				
HORIZON-2020	RABIOPRED	2015	100+25%	X	X	9.5/10
	ADDIA	2015		X	X	

SME POINT-OF-VIEW

With Horizon-2020 program, "innovative ideas" and "SMEs" are correctly privileged. SMEs are empowered to lead the "outcome oriented", high market value projects with potential strong societal impact.

IMI projects - Budget Management

<http://btcure.eu/>



<http://www.imi-safe-t.eu/>



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|--|--|
| <ul style="list-style-type: none"> - Beneficiaries Budget control by the Applicant Consortium Coordinator - Coordination and budgetary issues are handled <u>smoothly</u>. | <ul style="list-style-type: none"> - Coordination & Budget control by the EFPIA Consortium - Significant budget management issues - Final reporting done in Sept 2015 - Final payment ~300k €* still pending
<i>* an important issue for an SME!</i> |
|--|--|

SME POINT-OF-VIEW

SME facts are better known by the Applicant Consortium, which handles project grant management with more sensibility and attention towards SMEs.

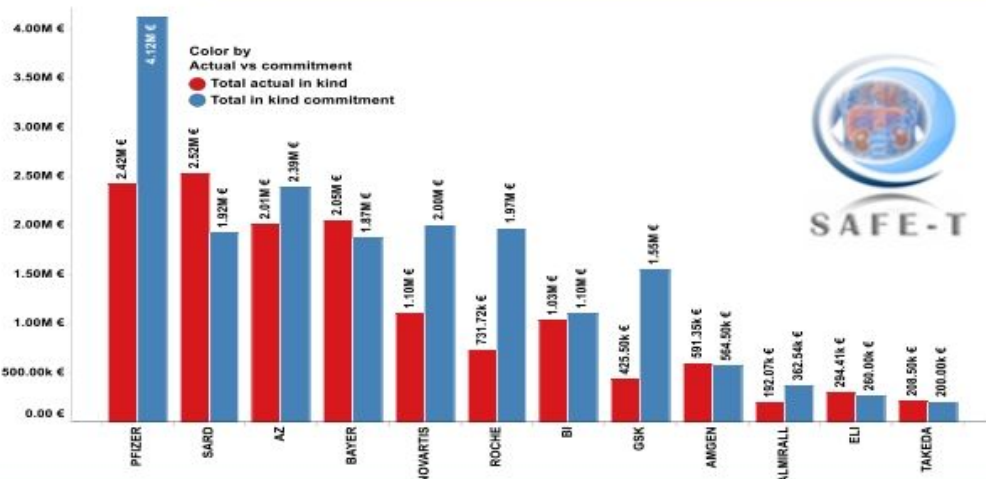
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Three IMI Projects, Lessons learned

EFPIA in-kind contribution is often significantly below target



- EFPIA in-kind contributions to be specified in more detail from the start of projects and the initial commitment shall be respected
- Need realistic commitment, EFPIA partners must have IMI within their objectives

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H-2020, SME-Instrument

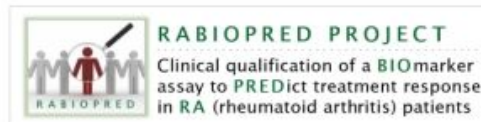


Experience from 2 ongoing projects

Amoneta Diagnostics SAS



Tc Land Expression SA



Today both projects are 1 y-old already, some feedbacks;

- **Direct coordination by empowered SMEs** : Accelerating the speed of project realization ensuring timely execution of projects.
- **Direct budgetary control** by SMEs : Subcontractors are better managed and « best value for money » is better guaranteed. Negotiations are better handled as SMEs care more financials.

Digitalization of European Commission



How it affects SME lives & projects



Removal of paper-wise communication

- Faster reporting
- More compact management tool for Coordinator
- Open communication door 7/24

Introduction of continuous reporting tool

- SMEs can manage easily the project execution and timely coordination
- Focus on innovation much less distracted
- Lesser management outsourcing = EU-wide savings

Thanks to European Grants

- Fully Integrated Biomarker platforms for precision medicine products
- Networks of academics, clinical centers of excellence, and big industrials



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Thank you

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