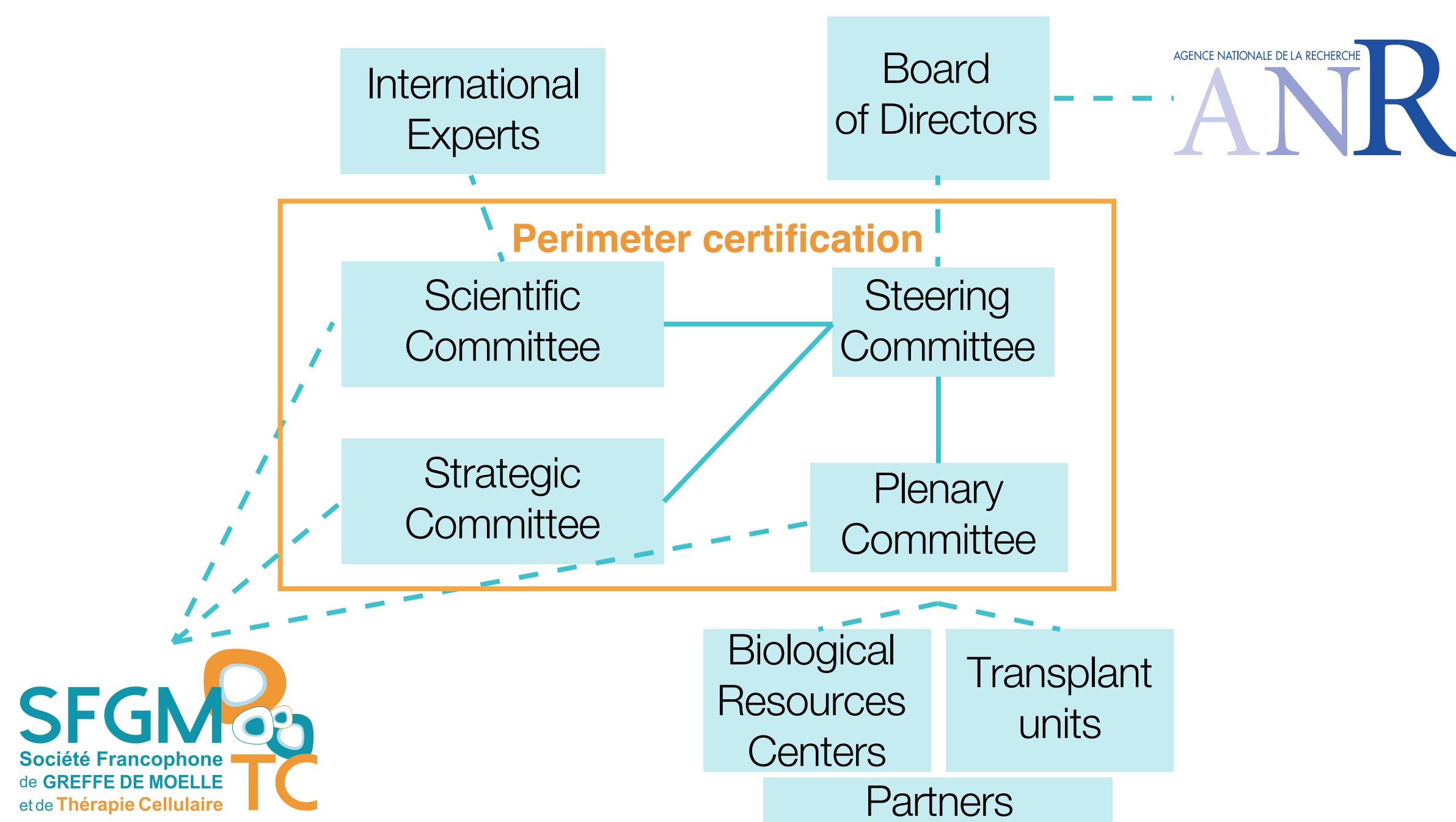


Benefits of ISO 9001 certification in large multi-center cohorts: feedbacks of CRYOSTEM

1 Introduction

CRYOSTEM is a French translational research network focused on post-allogeneic Hematopoietic Stem Cell Transplantation (HSCT) complications. The French Society for Stem Cell Transplantation and Cell Therapy (SFGM-TC) is a founding member of the network. CryoStem has been selected and funded to the extent of 5,8 millions € over a period of 9 years by the French Government's Investissements d'Avenir 2010 program. CryoStem brought together 33 out of 36 French HSCT Units and 23 Biological Resources Centers (BRC) that contribute to a prospective, longitudinal and standardized HSCT samples collection with concomitant well annotated clinical data. CryoStem maintains a standardized collection of high-quality samples to provide academic and industrial researchers with homogeneous samples for large-scale research. Therefore, the network governance decided to commit in early 2014 to a quality approach towards ISO 9001 certification, successfully obtained in February 2015.

2 Governance structure



3 ISO 9001 norm



ISO 9001 norm is an international quality management norm. It defines the requirements to meet/answer a Quality Management System (QMS), focusing on the customers needs and satisfaction, as well as on the motivation and commitment of management, process control and continuous improvement.



4 What are the benefits?

Internal Benefits	
Better understand issues to better adapt	REQUIREMENTS
Anticipate risks	PERFORMANCE
Involve teams around a common project	EFFICIENCY
Measure performance and progress	RECOGNITION
Optimize internal operations through continuous improvement	TRUST
Standardize practices within the network	Internal Benefits
Develop partners skills	Provide products and services related to customer requirements
Lower the costs	Improve customer satisfaction
	Strengthen the confidence of stakeholders (partners, providers, communities...)
	Enhance and recognize the quality commitment of the network

5 Conclusion

Benefits of ISO 9001 certification in large multi-center cohort are felt mainly at two levels:

Organizational level

- Structuration in **processes**
- Identification of dysfunctions, inefficient methods
- Facilitation of management and **communication**
- Activity and efficacy monitoring through specific **indicators**

Strategic level

- Certification delivered by **independent** organisms
- **International** visibility (as opposed to AFNOR)
- Demonstrate the **quality** of the Collection
- Demonstrate the **commitment** of all partners
- Focus on **users** expectations and satisfaction

ISO 9001 certification clearly plays a role in the network success and cohesion



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