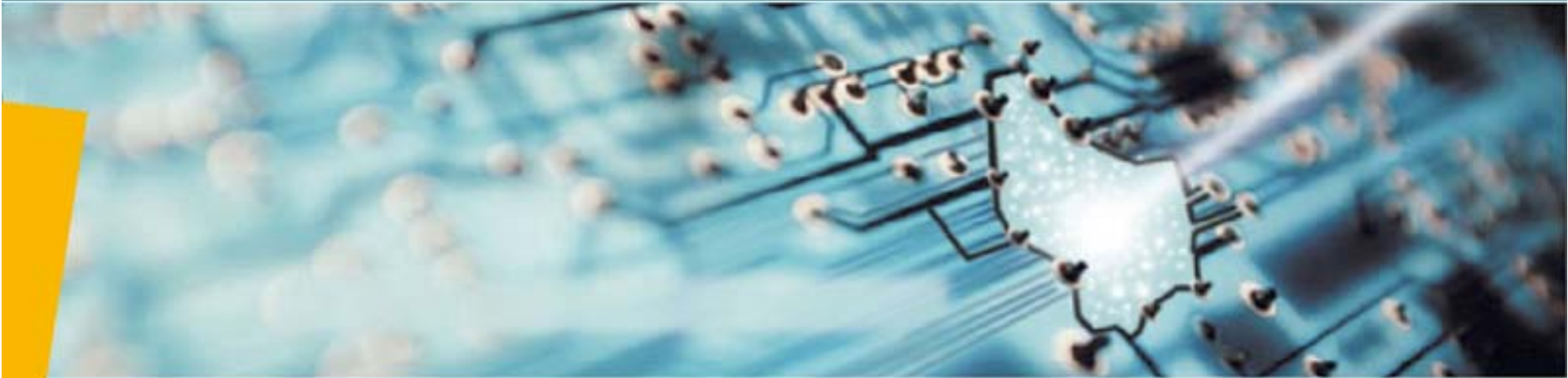


ILNAS



Standards in the field of biomedical technologies: A contribution for the national market

Business Meets Research 2012 – Forum Luxinnovation
Luxembourg – 22 May 2012

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1. Standardization in Luxembourg

ILNAS:

Institut Luxembourgeois de la Normalisation, de l'Accréditation, de la Sécurité et qualité des produits et services (public administration created by Law of 20th May 2008)

Standardization Strategy for Luxembourg (2010-2020):

- Initiated by the governmental program in 2009
- Established by ILNAS for the next decade and approved by the Minister of Economy and Foreign Trade (June 2010)

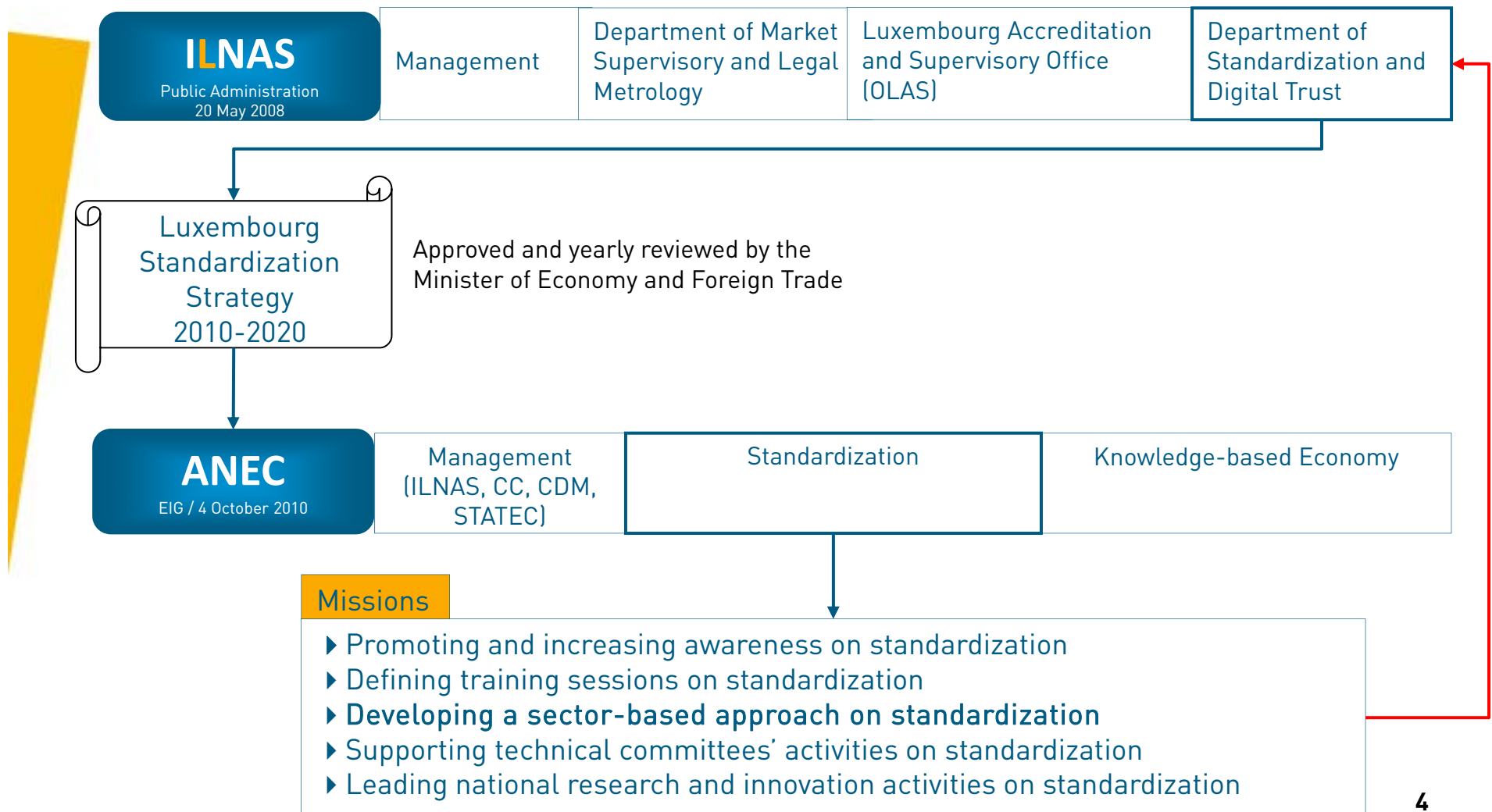
A sector-based normative approach as a support for the national economy:

- Facilitate access to the standards (**Reading notion – “User”**)
- Facilitate and encourage the participation in standardization (**Writing notion – “Builder”**)
- Selected sector: Biomedical Technologies (after ICT & Energy sectors)

ANEC:

Agence pour la Normalisation et l'Economie de la Connaissance (EIG created the 4th October 2010)

Organization:



2. Normative analysis of the national biomedical technologies sector

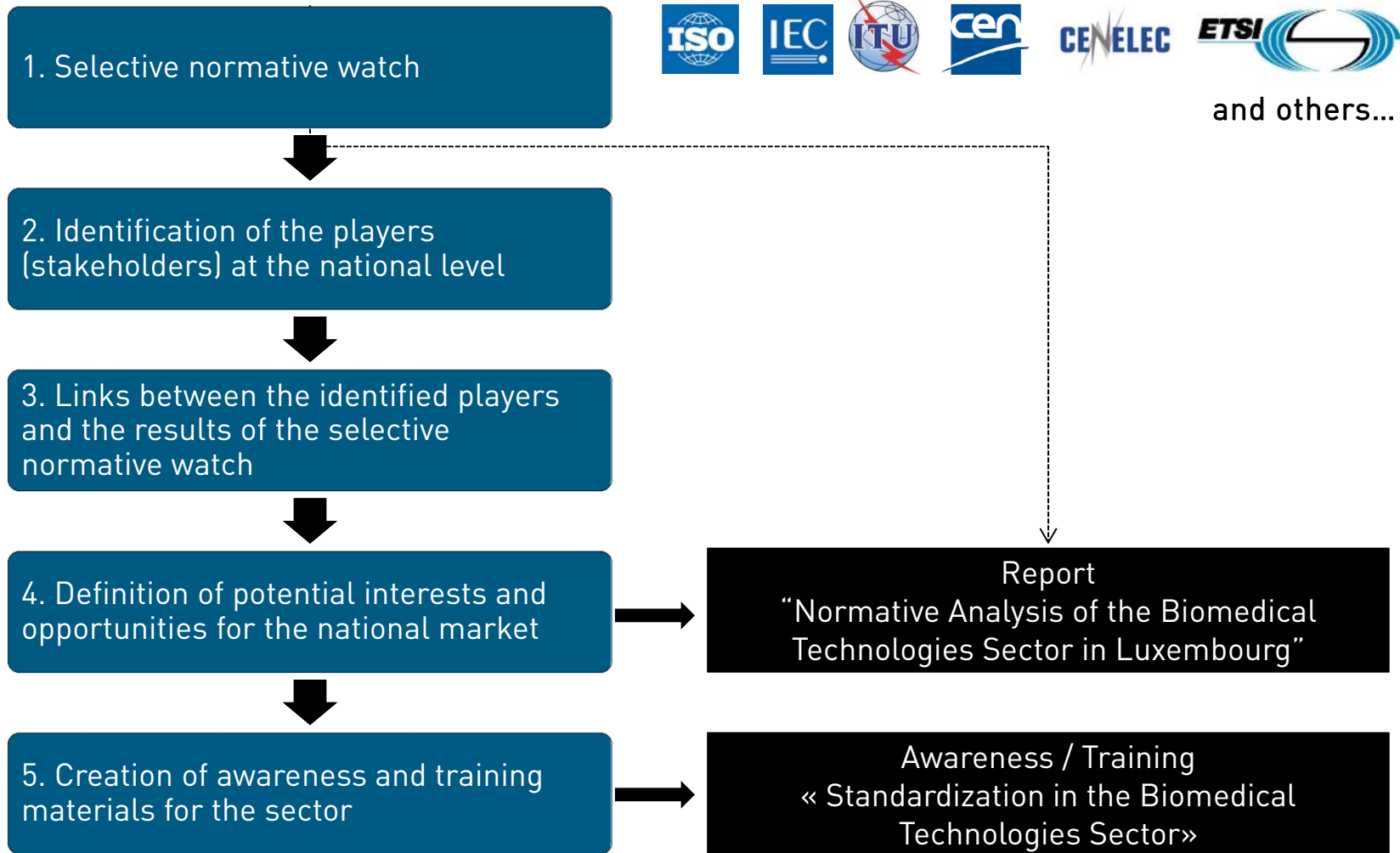
2.1. Goals of the normative analysis

- ↪ Inform the national players about standardization developments in their sector
- ↪ Identify potential interests for the national players and opportunities for the national market
- ↪ Encourage all players of a sector to have a normative reflex
- ↪ Develop « standards-related » skills and collaborations between players of a sector

2.2. Definition of the national biomedical technologies sector

- ↪ Made in concertation with the Ministry of Economy and Foreign Trade
- ↪ Focus on Biomedical Technologies
- ↪ Potential subsectors: Pharma, Diagnostics, Medical devices, Health informatics, Hospitals, etc.
- ↪ Dentistry included, Veterinary activities excluded

2.3. Methodology of the normative analysis



2.4. First results of the normative analysis


► Selective normative watch (Status: 15.05.2012)

Selection of active TCs in terms of “*current, dynamic and strategic*”

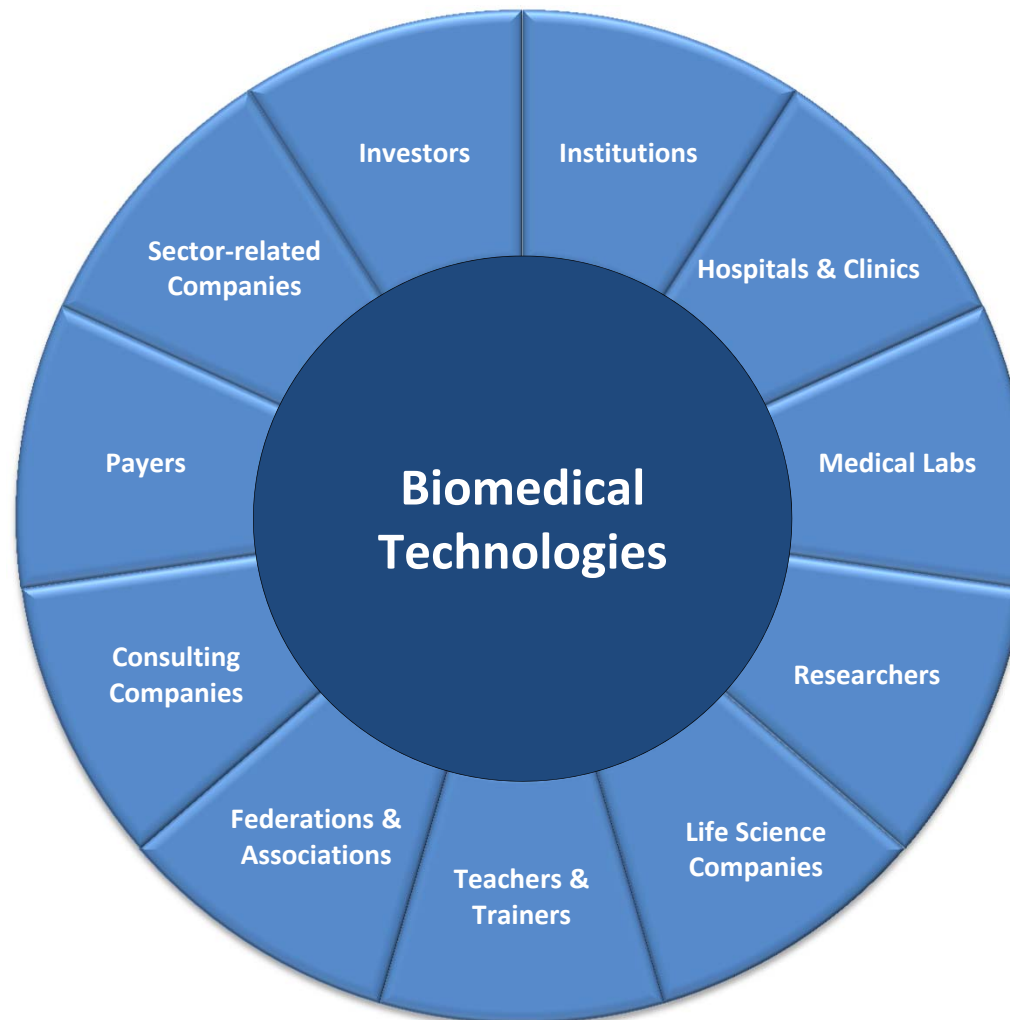
↳ 40 « active » standardization technical committees for the biomedical technologies sector

Subsectors	European Standardization Technical Committees	International Standardization Technical Committees	Total
[Sub-1] Medical Devices	2	7	9
[Sub-2] Medical Equipment	4	6	10
[Sub-3] Medical Services	5	1	6
[Sub-4] Diagnostics	5	3	8
[Sub-5] eHealth	3	4	7
Total	19	21	40

▶ Selective normative watch

General Information			
Creation Date		Title of the Technical Committee	
Secretariat			
Secretary			
Chairperson			
Organizations in liaison			
Subcommittees / Working groups			
Participating Members 		Observing Members	
Total		Total	
Participation of Luxembourg		National delegates	
European Directives			
Standardization Mandates			
Business Plan			
Version			
Scope			
Executive summary			
Work Programme			
Published standards			
Standards under development			
Comments			

► Identification of the national players (Status: 15.05.2012)



Sources:

Contacts, publications, reports, internet, meetings

▶ Potential interests for the national players

Goal:

Provide links between the categories of players and the biomedical technologies subsectors as they were defined in the initial stage of the selective normative watch

Potential interests:

◆ **Information:**

↪ Learn about standards developments

■ **Performances:**

↪ Increase performances (networking/benchmarking)

❖ **Services:**

↪ Develop new services

□ **Projects:**

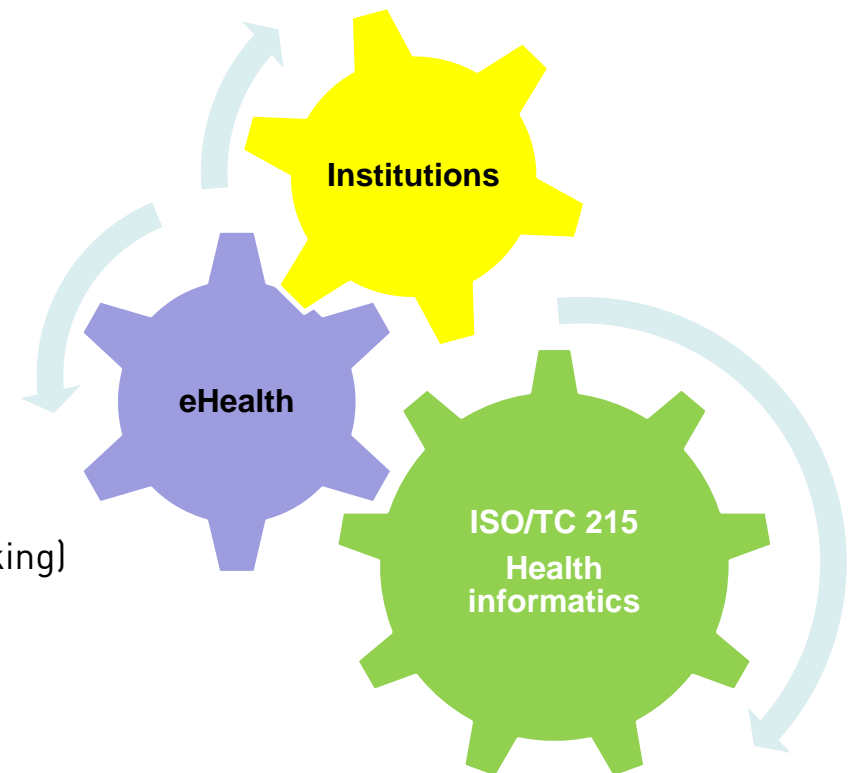
↪ Follow or participate in research projects

● **Training:**

↪ Update or develop training sessions

\$ **Investments:**

↪ Invest in a new technology



Results:

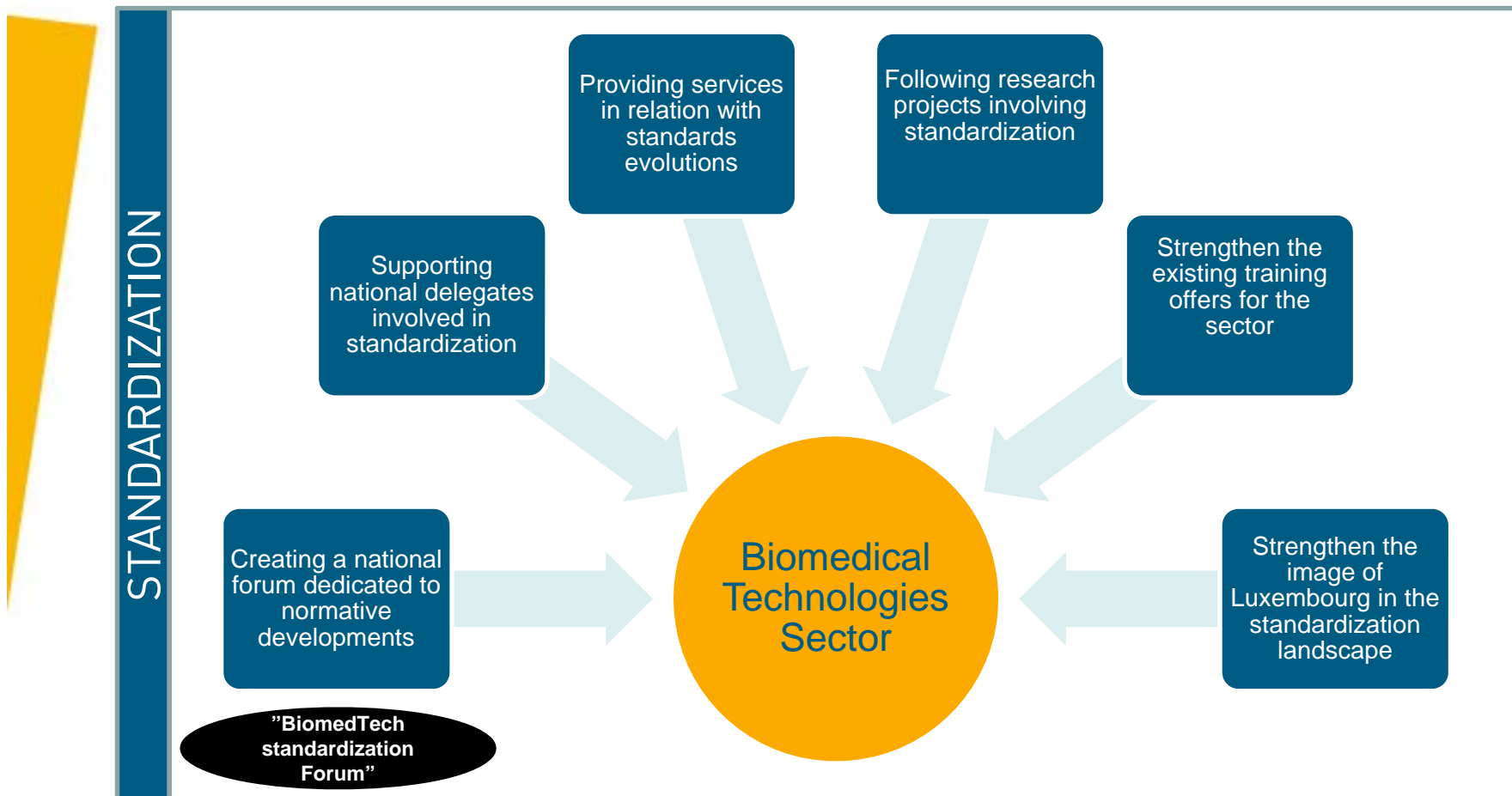
Results will be presented through:

- a specific matrix for each category of players (as presented below)
- a final matrix with all categories of players

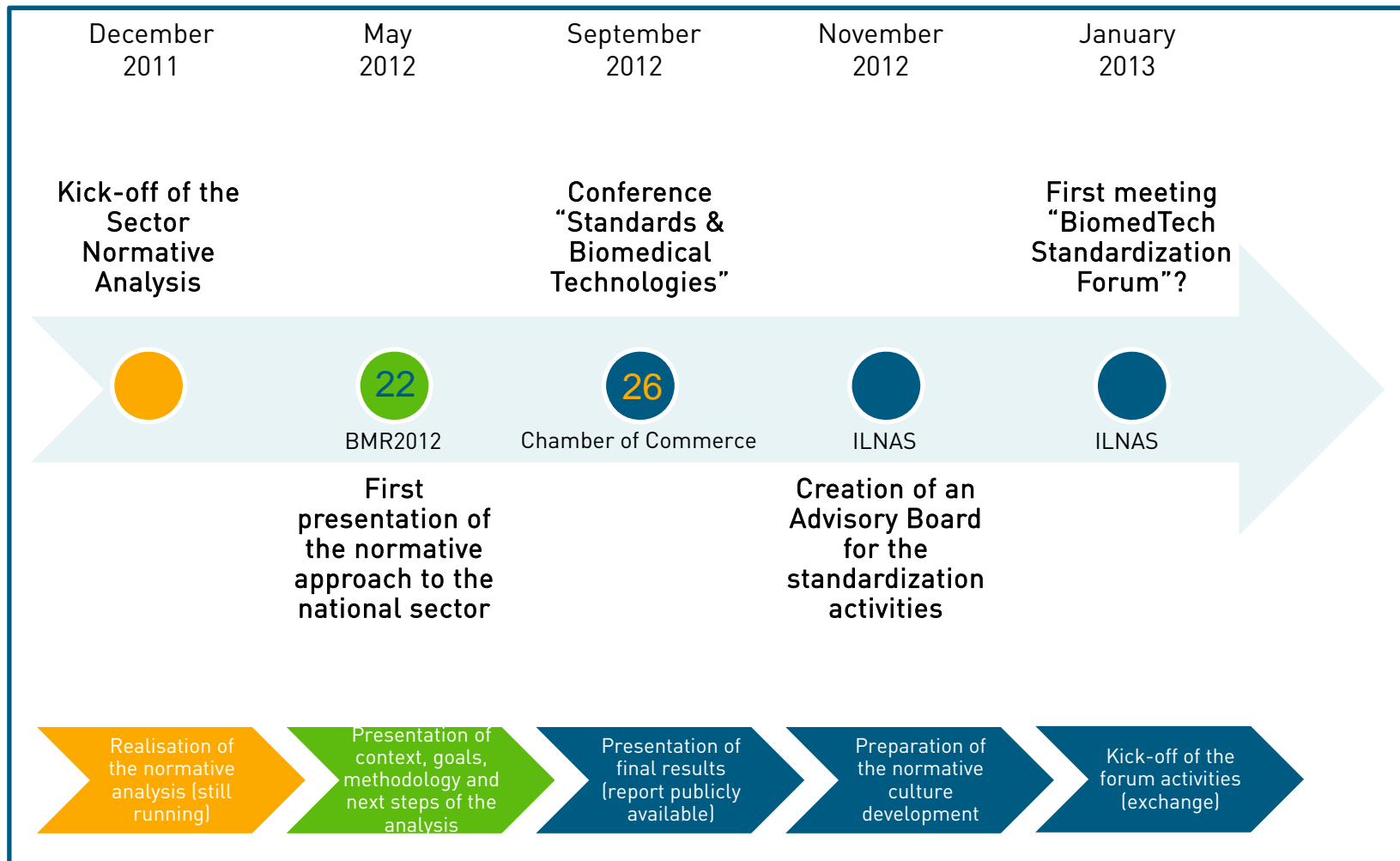
Example of a specific matrix:

Matrix of normative analysis	[Sub-1] Medical Devices (9 TCs)	[Sub-2] Medical Equipment (10 TCs)	[Sub-3] Medical Services (6 TCs)	[Sub-4] Diagnostics (8 TCs)	[Sub-5] eHealth (7 TCs)	Comments
Institutions						
Information	X	X	X	X	X	
Performances						
Services					X	
Projects				X	X	
Training					X	
Investments	X	X	X	X	X	

► Opportunities for the national market



3. Next steps



4. Message

- Regarding Standards and Standardization in Luxembourg:
 - ↳ Have the good reflex « ILNAS & ANEC » - www.ilnas.lu
- Regarding the use of standards (Reading notion – “User”):
 - ↳ The ILNAS e-shop will be available soon (June 2012)
- Regarding the participation in the standardization process (Writing notion – “Builder”):
 - ↳ There is no participation fee after a prior registration at ILNAS
- Regarding the normative analysis of the biomedical technologies sector in Luxembourg:
 - ↳ Don't miss the presentation of the results in the frame of the **Conference “Standards & Biomedical technologies”**
26 September 2012 at the Chamber of Commerce



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Responsible for Cross-sectors Standardization Development

Agency for Standardization and knowledge-based Economy (EIG)

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