

Standards analysis of the biomedical technologies sector

Main results and opportunities

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Conference “Standards in the biomedical technologies sector: Challenges & opportunities for the national market”

Luxembourg, 26 September 2012

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1. Standards analysis of the national biomedical technologies sector

Objective

Support specific sectors of activities identified by the Minister of the Economy and Foreign Trade as promising for the national economic market.

The aims are to:

- Inform the national stakeholders about standardization developments in their sector
- Identify potential interests for the national stakeholders and opportunities for the national market
- Support players of a given sector in their standardization activities
- Develop « standards-related » skills and collaboration between the stakeholders of a sector

Implementation of a standards analysis dedicated to a specific sector

- Identification of the sector in coordination with the Ministry of the Economy and Foreign Trade

Biomedical technologies

- Definition of the scope of the analysis

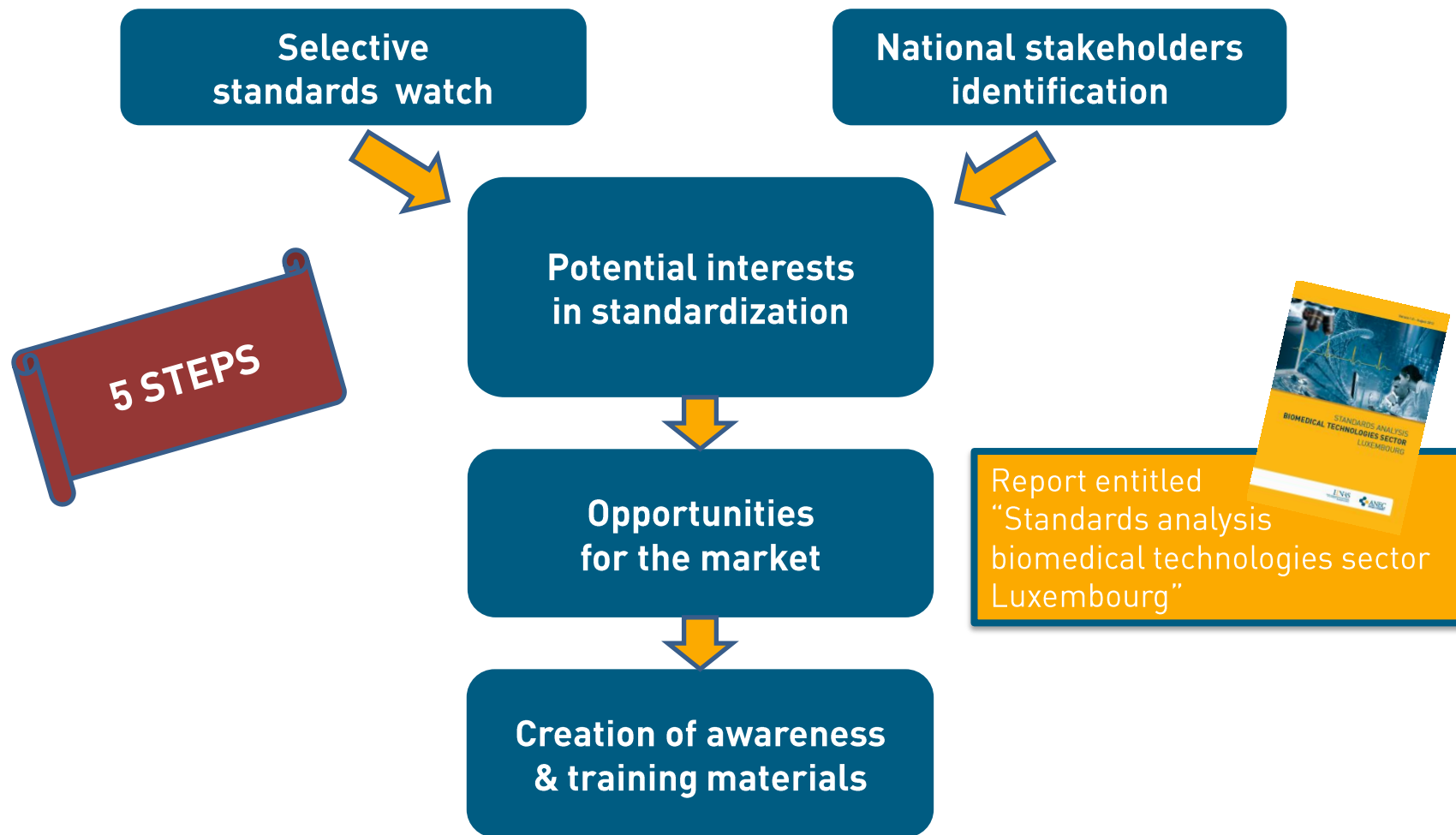
All the biomedical activities including dentistry but excluding veterinary activities

- Preparation and achievement of the analysis
- Presentation of the results

Publication & Conference



Methodology of the standards analysis



2. Selective Standards Watch

2.1. Objective

Identification of the standardization activities under going and potentially interesting for the sector.

2.2. Methodology

- Identification of **all the technical committees (TC) related to the biomedical technologies sector**:
 - ✓ Technical committees of formal standards bodies at international, European or national level and other non-formal standards bodies

Formal standards bodies

	National level	European level	International level
General scope	 <p>Institut luxembourgeois de la normalisation, de l'accréditation, de la sécurité et qualité des produits et services</p>		
Focused on Electrotechnology	 <p>Institut luxembourgeois de la normalisation, de l'accréditation, de la sécurité et qualité des produits et services</p>		
Focused on Telecommunications	 <p>Institut luxembourgeois de la normalisation, de l'accréditation, de la sécurité et qualité des produits et services</p>		

Other standards bodies, e.g.:

HL7
Health Level Seven
International

DICOM
Digital imaging and
communication in medicine

ITU-T
International
Telecommunication Union

IHE
Integrating the
Healthcare Enterprise

2. Selective Standards Watch

2.1. Objective

Identification of the standardization activities under going and potentially interesting for the sector.

2.2. Methodology

- Identification of **all the technical committees (TC) related to the biomedical technologies sector**:
 - ✓ Technical committees of formal standards bodies at international, European or national level and other non-formal standards bodies
 - ✓ ICS code, key words as health, medical, diagnostic, medicine, laboratory...
 - ✓ Regulatory context
 - ✓ European mandates from the European Commission
 - ✓ News of the sector
- Selection of specific standardization technical committees in terms of being **current, dynamic and strategic**
- Subdivision of the biomedical technologies sector into subsectors and **classification of the selected TC accordingly**

2.3. Results of the selective standards watch

- Identification of 121 standardization technical committees (TC)
- Selection of the **42 TCs** considered as the most active standardization technical committees in terms of being **current, dynamic and strategic**
- Distribution in **5 subsectors**:
 - Subsector 1 - Medical devices sector
 - Subsector 2 - Medical equipment sector
 - Subsector 3 - Medical services sector
 - Subsector 4 - Diagnostics sector
 - Subsector 5 - eHealth sector



From the European Commission, eHealth is “the ICT tools and services for health. It covers the interaction between patients and health-service providers, institution-to-institution transmission of data, or peer-to-peer communication between patients and/or health professionals.”

Distribution of the selected technical committees in the biomedical technologies sector

Biomedical technologies subsectors	European technical committees	International technical committees	Total
Medical devices	2	8	10
Medical equipment	5	6	11
Medical services	5	0	5
Diagnostics	6	3	9
eHealth	3	4	7
Total	21	21	42

[In detail...](#)

Technical committees selected in the subsector 1 - Medical devices

CEN/TC 205 - Non-active medical devices

CEN/CLC/JWG/AIMD - CEN/CENELEC Joint Working Group on Active Implantable Medical Devices

ISO/TC 76 - Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use

ISO/TC 84 - Devices for administration

ISO/TC 106 - Dentistry

ISO /TC 150 - Implants for surgery

ISO/TC 157 - Non-systemic contraceptives

ISO/TC 168 - Prosthetics and orthotics

ISO/TC 170 - Surgical instruments

ISO/TC 210 - Quality management and corresponding general aspects for medical devices

Standard ISO 13 485 - Medical devices

Quality management systems - Requirements for regulatory purposes

Published in 2003 and currently under revision.

It specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.

Technical committees selected in the

CEN/TC 102 - Sterilizers for medical purposes

CEN/TC 215 - Respiratory and anaesthetic equipment

CEN/TC 239 - Rescue systems

CEN/TC 332 - Laboratory equipment

CENELEC/TC 62 - Electrical equipment in medical practice

ISO/TC 48 - Laboratory equipment

ISO/TC 121 - Anaesthetic and respiratory equipment

ISO/TC 172 - Optics and photonics

ISO/TC 173 - Assistive products for persons with disabilities

ISO/TC 198 - Sterilization of health care products

IEC/TC 62 -Electrical equipment in medical practice

ISO SO/IEC Guide 63 - Guide to the development and inclusion of safety aspects in International Standards for medical devices

Published in 2012 and prepared jointly by IEC/SC 62A and ISO/TC 210. To create a coherent approach to the treatment of safety in the preparation of standards, close coordination within and among committees responsible for different medical devices is necessary.

Standard ISO 20 857 Sterilization of health care products - Dry heat - Requirements for the development, validation and routine control of a sterilization process for medical devices

Published in 2010, it specifies requirements for the development, validation and routine control of a dry heat sterilization process for medical devices.

Technical committees selected in the subsector 3 - Medical services

CEN/TC 362 - Project Committee - Healthcare services - Quality management systems

CEN/TC 394 - Project Committee

CEN/TC 403 - Project Committee

CEN/TC 414 - Project Committee

CEN/WS 068 - CEN Workshop

CEN/EN 15 224 - Health care services - Quality management systems Requirements based on EN ISO 9001:2008

In process to be published.

This is a sector specific quality management system standard for health care organizations based on ISO 9001:2008. The requirements have been modified and clarified according to the specific health care context.

Technical committees selected in the subsector 4 - Diagnostics

CEN/TC 140 - In vitro dia

CEN/TC 216 - Chemical c

CEN/TC 347 - Methods f

CEN/TC 367 - Breath-alc

CENELEC/BTTF 116-2- A

CEN/WS 055 - Guidance

ISO/TC 194 - Biological evaluation of medical devices

ISO/TC 209 - Cleanrooms and associated controlled environments

ISO/TC 212 - Clinical laboratory testing and in vitro diagnostic test systems

Standard ISO 14 155 - Clinical investigation of medical devices for human subjects Good clinical practice

Revised in 2011.

It addresses good clinical practice for the design, conduct, recording and reporting of clinical investigations carried out in human subjects to assess the safety or performance of medical devices for regulatory purposes.

It does not apply to in vitro diagnostic medical devices.

Standard ISO/EN 15 189 - Medical laboratories Requirements for quality and competence

Important for the accreditation process to confirm or recognize the quality management systems and competence of medical laboratories.

Published in 2003 and currently under revision.

Technical committee

Standard ISO 27 799 - Health informatics – Information security management in health using ISO/IEC 27002

CEN/TC 251 - Health informatics

Published in 2008.

ETSI Project EP eHealth

The standard specifies a set of detailed controls for managing health information security and provides health information security best practice guidelines.

CEN/CENELEC/ETSI Project

ISO/TC 215 - Health informatics

ITU/ITU-T Study Group 1

Standard ISO/TS 14 265 - Health Informatics - Classification of purposes for processing personal health information

DICOM - Digital imaging and communications in medicine

HL7 - Health Level Seven

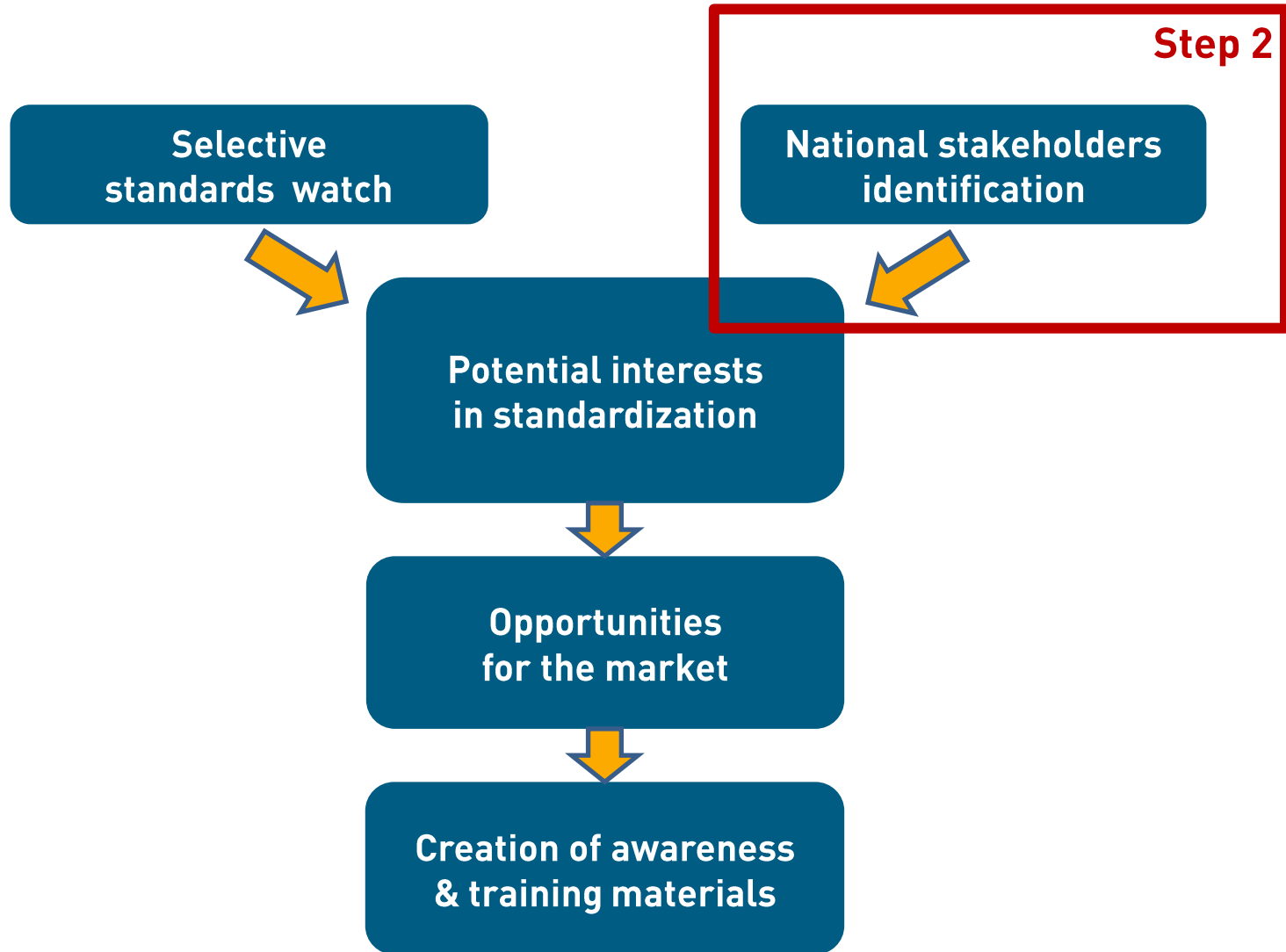
Published in 2011.

This standard defines a set of high-level categories of purposes for which personal health information can be processed.

ID-Card

Presentation of the results using identification **ID-cards** for each standardization technical committees

General Information			
Creation Date		<p style="text-align: center;">Title of the Technical Committee</p>	
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			



3. National stakeholders identification

3.1. Objective

Identification of national private and public stakeholders representing the entire biomedical technologies sector in Luxembourg to simplify the proposals of connections between the categories of stakeholders and the biomedical technologies subsectors classifying the selected TCs.

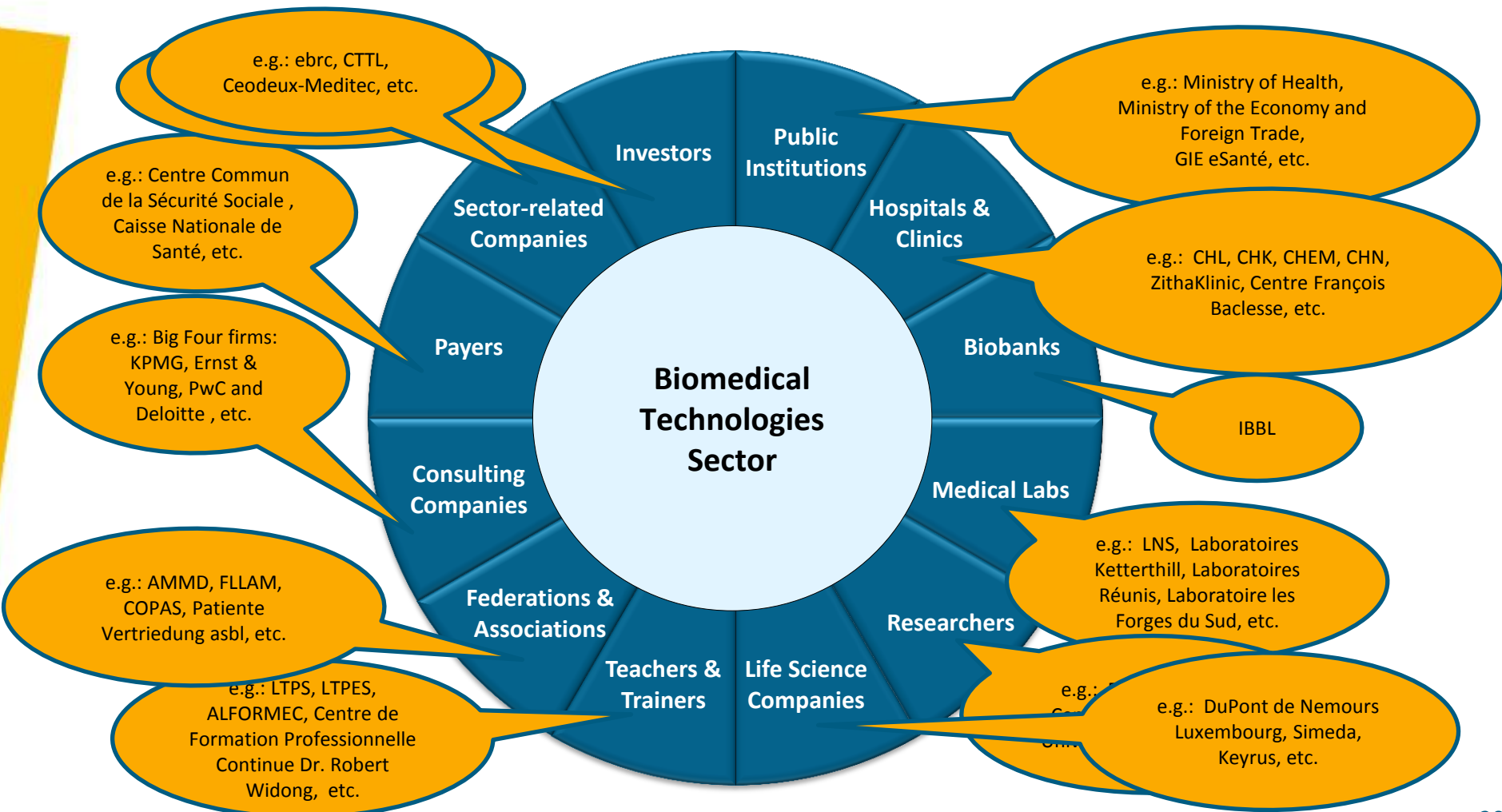
3.2. Methodology

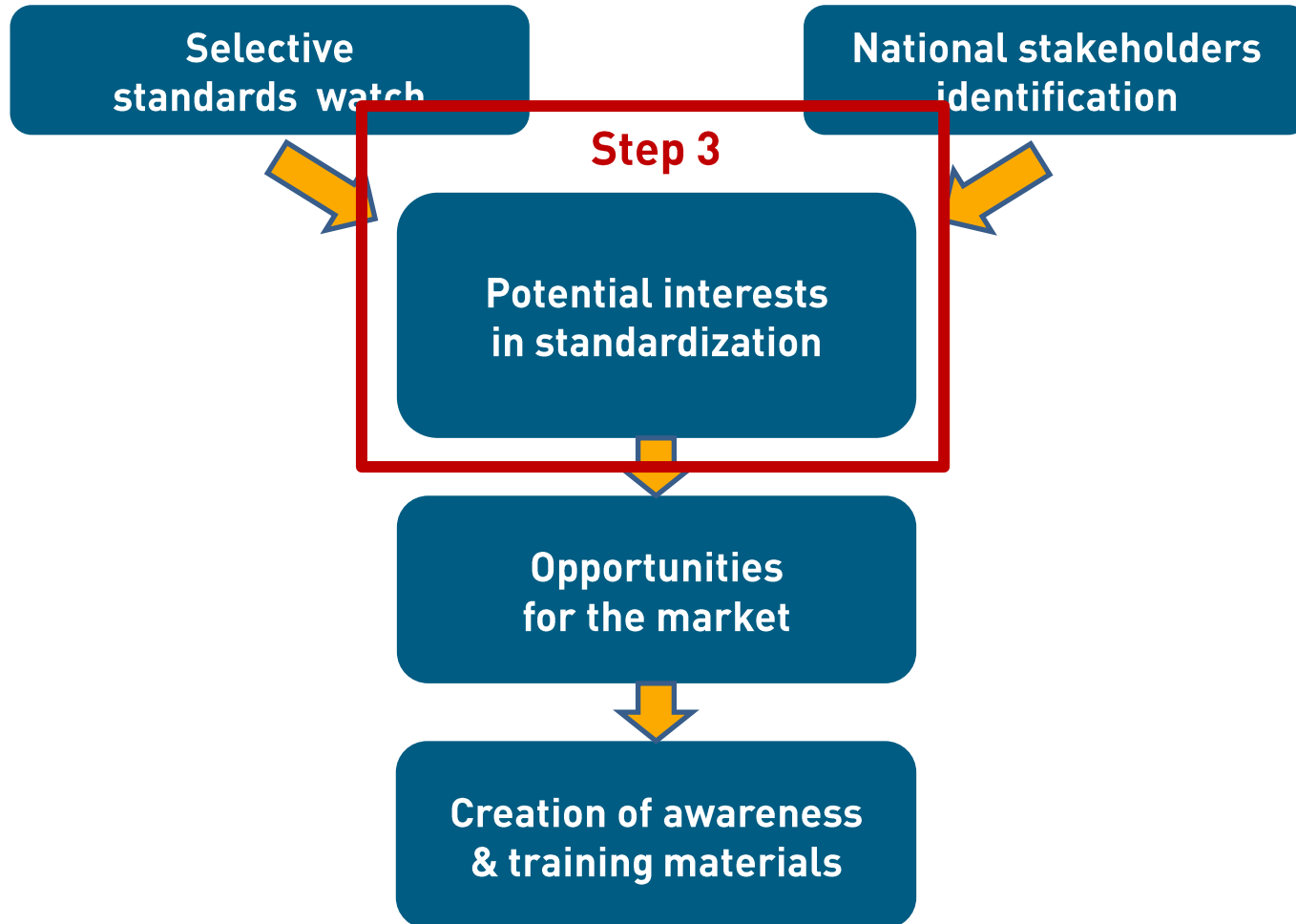
- Identification of the public and private stakeholders acting in the biomedical technologies sector
- Identification of the connections, relationships between the stakeholders
- Definition of categories of stakeholders

Sources: contacts, publications, reports, internet, meetings, etc.

Result: A picture as full and complete as possible of the biomedical technologies sector in Luxembourg

3.3. Overview of the national stakeholders of the biomedical technologies sector





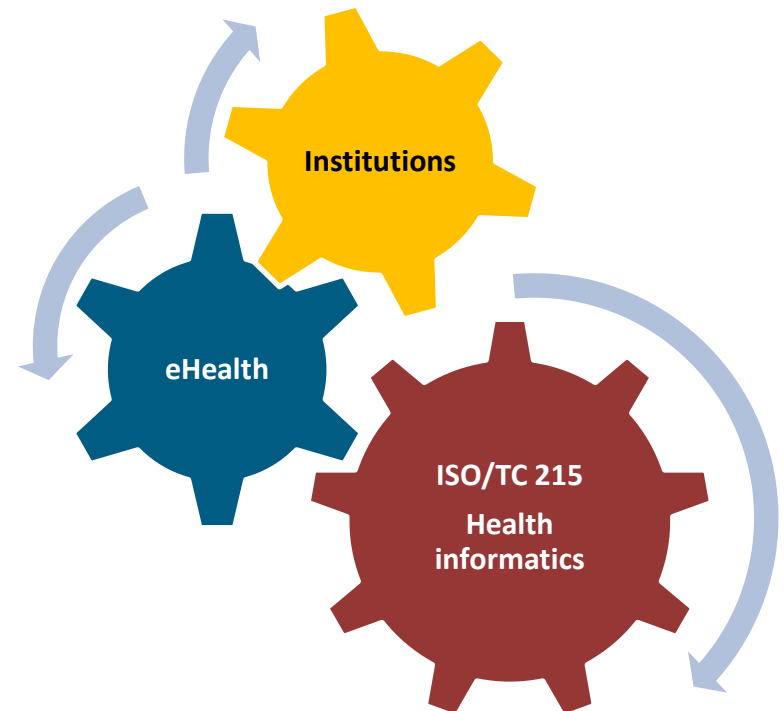
4. Potential interests in standardization

4.1. Objective

Provide links between a category of stakeholders with biomedical technologies subsectors as identified in the initial stage of the standards analysis according to their potential interests in standardization.

4.2. Methodology

- Design of a matrix for each category of stakeholders
- Details of the different potential interests in each subsectors



Definition of 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

4.3. Results

Public Institutions

	Subsector 1 Medical devices	Subsector 2 Medical equipment	Subsector 3 Medical services	Subsector 4 Diagnostics	Subsector 5 eHealth
Information	X	X	X	X	X
Performance	X	X	X	X	X
Services					X
Projects					X
Training					
Investments	X	X	X	X	X

- ↪ Important to maintain a good level of information on all the subsectors
- ↪ Interest in developing and acquiring new competencies and, thus, increasing performance
- ↪ Interest in following all the biomedical technologies subsectors in terms of investments

Hospitals & Clinics

	Subsector 1 Medical devices	Subsector 2 Medical equipment	Subsector 3 Medical services	Subsector 4 Diagnostics	Subsector 5 eHealth
Information	X	X	X	X	X
Performance	X	X	X	X	X
Services			X	X	X
Projects				X	X
Training					
Investments					X

- ⇒ Important to maintain a good level of information on all the subsectors, especially to increase their performance
- ⇒ Develop news services especially in the Medical services, Diagnostics and eHealth subsectors
- ⇒ Opportunities to participate and collaborate in research projects, especially in Diagnostics and eHealth subsectors

Biobanks

	Subsector 1 Medical devices	Subsector 2 Medical equipment	Subsector 3 Medical services	Subsector 4 Diagnostics	Subsector 5 eHealth
Information	X	X	X	X	X
Performance		X	X	X	
Services			X	X	
Projects				X	X
Training					
Investments				X	X

- ↪ Important to maintain a good level of information on all the subsectors, especially to increase their performance and to develop new services dedicated to Diagnostics
- ↪ Interest to participate in research projects especially in Diagnostics and eHealth subsectors
- ↪ Support in terms of potential investments in domains largely influenced by new technologies

Medical Laboratories

	Subsector 1 Medical devices	Subsector 2 Medical equipment	Subsector 3 Medical services	Subsector 4 Diagnostics	Subsector 5 eHealth
Information	X	X	X	X	X
Performance		X	X	X	
Services			X	X	X
Projects					X
Training					
Investments				X	X

- ⇒ Important to maintain a good level of information on all the subsectors, especially to increase performance and to develop new services dedicated to Diagnostics or eHealth subsectors
- ⇒ Interest to participate in research projects especially in eHealth subsector
- ⇒ Support in terms of potential investments in domains largely influenced by new technologies as Diagnostics or eHealth subsectors

Researchers

	Subsector 1 Medical devices	Subsector 2 Medical equipment	Subsector 3 Medical services	Subsector 4 Diagnostics	Subsector 5 eHealth
Information	X	X	X	X	X
Performance				X	X
Services				X	X
Projects				X	X
Training					
Investments					

- ⇒ Important to maintain a good level of information on all the subsectors to remain as close as possible to the state of the art
- ⇒ Improve their performance and develop new services through networking or benchmarking
- ⇒ Interest to participate in research projects especially in Diagnostics and eHealth subsectors

Life science companies

	Subsector 1 Medical devices	Subsector 2 Medical equipment	Subsector 3 Medical services	Subsector 4 Diagnostics	Subsector 5 eHealth
Information	X	X	X	X	X
Performance	X	X	X	X	X
Services				X	X
Projects				X	X
Training					
Investments	X	X	X	X	X

- ↪ Important to maintain a good level of information on all the subsectors and develop their performance
- ↪ Opportunities to improve and develop new services and to participate to projects through networking or benchmarking especially in Diagnostics and eHealth subsectors
- ↪ Support in terms of potential investments in the innovative biomedical technologies sector

Teachers & Trainers

	Subsector 1 Medical devices	Subsector 2 Medical equipment	Subsector 3 Medical services	Subsector 4 Diagnostics	Subsector 5 eHealth
Information	X	X	X	X	X
Performance					
Services					
Projects					
Training	X	X	X	X	X
Investments					

- ↳ Important to maintain a good level of information on all the subsectors to keep up the quality level of their trainings
- ↳ Opportunities to develop new trainings sticking to the last developments of the biomedical technologies sector

Federations & Associations

	Subsector 1 Medical devices	Subsector 2 Medical equipment	Subsector 3 Medical services	Subsector 4 Diagnostics	Subsector 5 eHealth
Information	X	X	X	X	X
Performance					
Services	X	X	X	X	X
Projects					
Training					
Investments					

↪ Important to maintain a good level of information on all the subsectors to conserve and improve the quality level of their services

Consulting companies

	Subsector 1 Medical devices	Subsector 2 Medical equipment	Subsector 3 Medical services	Subsector 4 Diagnostics	Subsector 5 eHealth
Information	X	X	X	X	X
Performance					
Services	X	X	X	X	X
Projects					
Training					
Investments					

- ↳ Important to keep a good level of information on all the subsectors to maintain a high level of expertise
- ↳ Opportunities to develop new services sticking to the last developments of the biomedical technologies sector

Payers

	Subsector 1 Medical devices	Subsector 2 Medical equipment	Subsector 3 Medical services	Subsector 4 Diagnostics	Subsector 5 eHealth
Information	X	X	X	X	X
Performance					
Services					
Projects					
Training					
Investments					

↳ Following standards activities should help them in maintaining a good level of information on all the subsectors

Sector-related companies

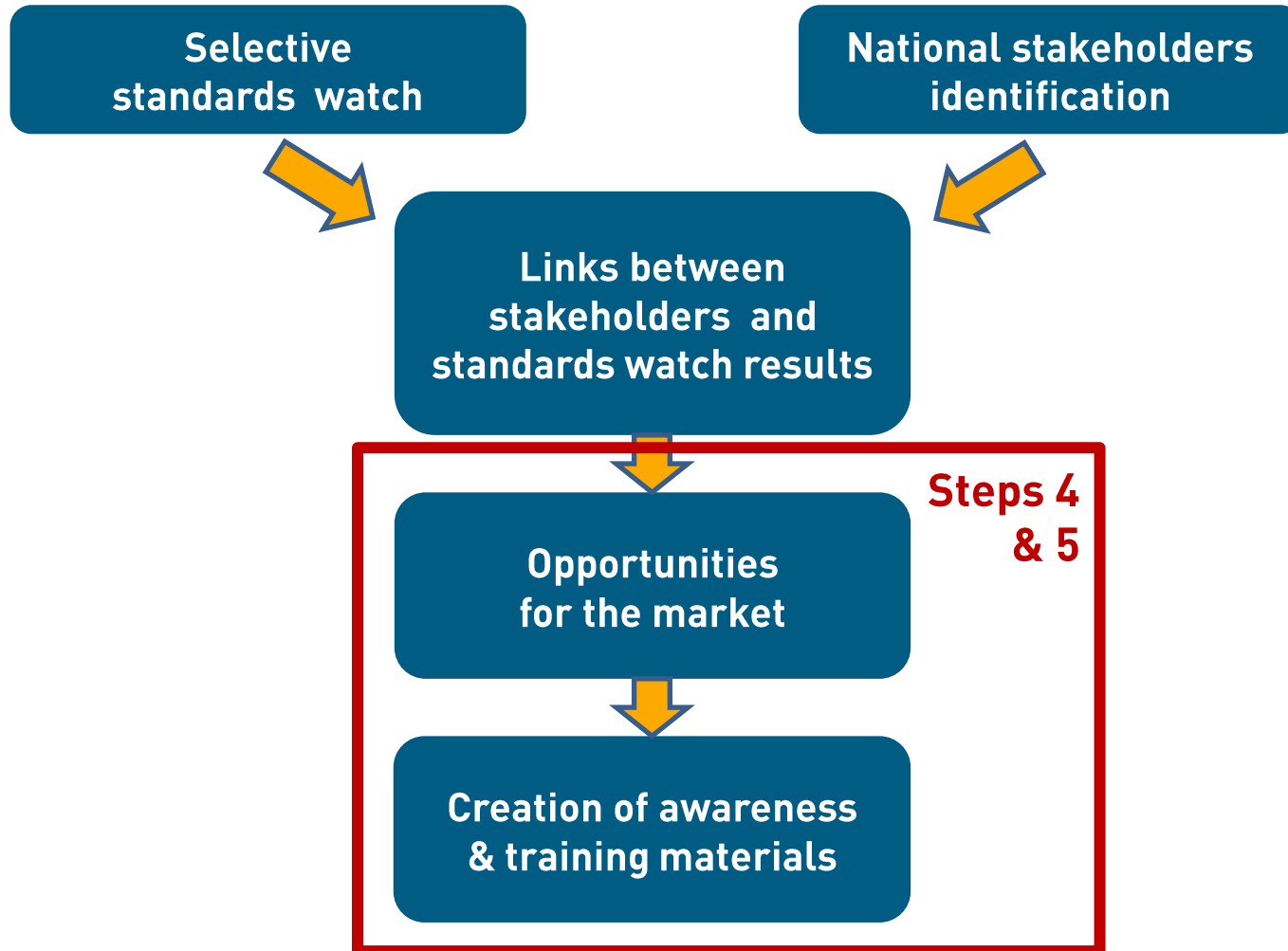
	Subsector 1 Medical devices	Subsector 2 Medical equipment	Subsector 3 Medical services	Subsector 4 Diagnostics	Subsector 5 eHealth
Information	X	X	X	X	X
Performance	X				X
Services	X				X
Projects					
Training					
Investments					

- ↳ Following standards activities should help them in maintaining a good level of information on all the subsectors
- ↳ Support the improvement of their performance and the development of new services especially in the Medical devices and eHealth subsectors

Investors

	Subsector 1 Medical devices	Subsector 2 Medical equipment	Subsector 3 Medical services	Subsector 4 Diagnostics	Subsector 5 eHealth
Information	X	X	X	X	X
Performance					
Services					
Projects					
Training					
Investments	X	X	X	X	X

↳ Following standards activities should help them in maintaining a good level of information on all the subsectors and support their decisions in term of potential investments



5. Opportunities for the national market

5.1. Global matrix of all potential interests shared between the national stakeholders

Biomedical technologies sector	Subsector 1 Medical devices	Subsector 2 Medical equipment	Subsector 3 Medical services	Subsector 4 Diagnostics	Subsector 5 eHealth
Public institutions	◆■\$	◆■\$	◆■\$	◆■\$	◆■❖\$
Hospitals & Clinics	◆■	◆■	◆■❖	◆■❖□	◆■❖□\$
Biobanks	◆	◆■	◆■❖	◆■❖□\$	◆□\$
Medical Labs	◆	◆■	◆■❖	◆■❖\$	◆❖□\$
Researchers	◆	◆	◆	◆■❖□	◆■❖□
Life Science Companies	◆■\$	◆■\$	◆■\$	◆■❖□\$	◆■❖□\$
Teachers & Trainers	◆○	◆○	◆○	◆○	◆○
Federations & Associations	◆❖	◆❖	◆❖	◆❖	◆❖
Consulting Companies	◆❖	◆❖	◆❖	◆❖	◆❖
Payers	◆	◆	◆	◆	◆
Sector-related Companies	◆■❖	◆	◆	◆	◆■❖
Investors	◆\$	◆\$	◆\$	◆\$	◆\$

◆ Information

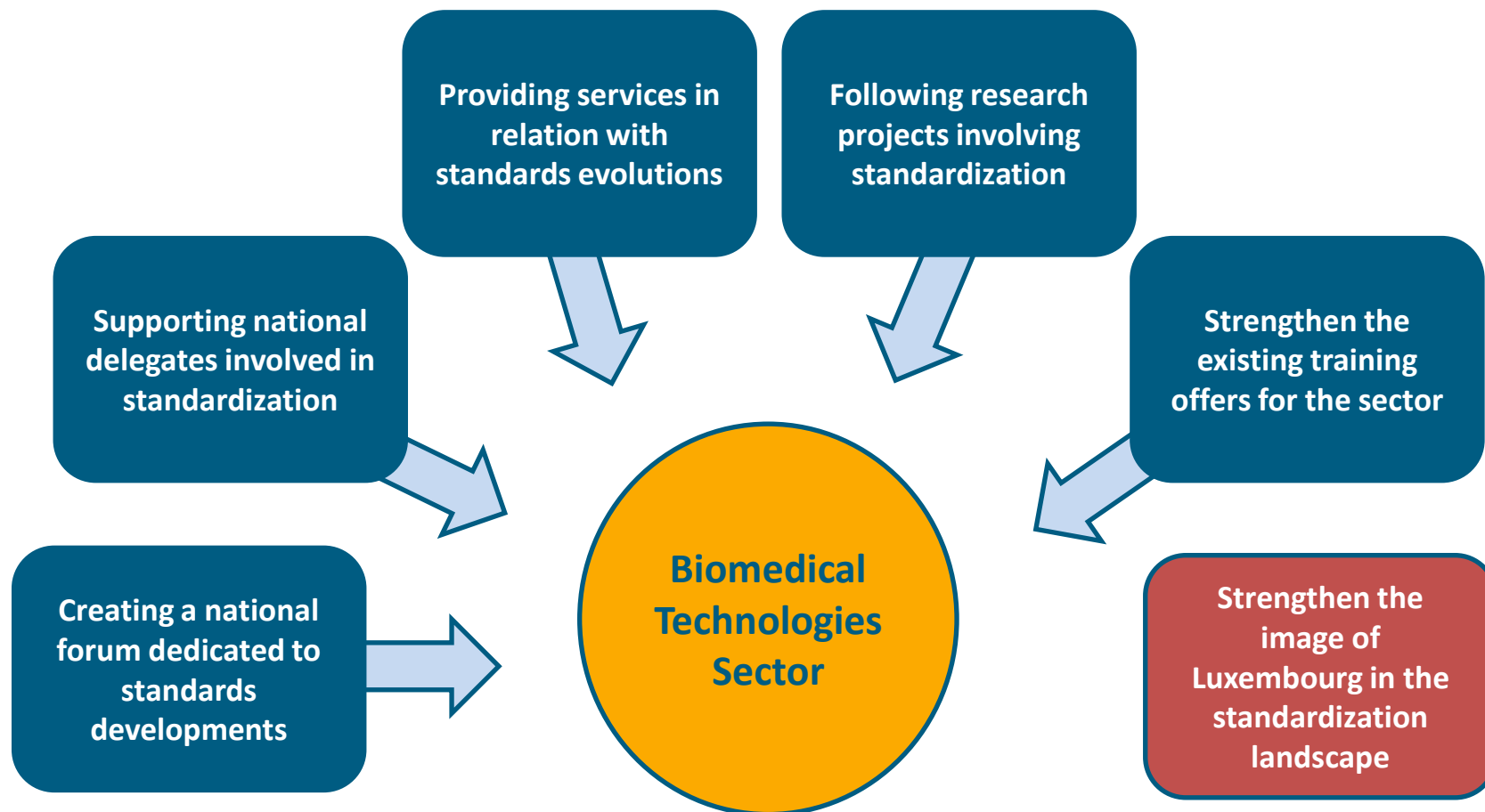
■ Performance

❖ Services

□ Projects

○ Training

\$ Investment



6. Conclusion & Next steps

The biomedical technologies sector is considered as a key innovation driver able to reinforce competitiveness and economic benefits through an innovative healthcare system

Standardization can support the national stakeholders by helping them to:

- Control risk and safety of their products
- Gain access to new markets
- Anticipate future developments
- Enhance expertise
- Meet and exchange with experts
- Etc.

The main goals of this standards analysis dedicated to the biomedical technologies sector are to:

- Present to the national stakeholders standardization technical committees of strategic importance
- Identify potential interests of the national stakeholders to participate to standardization activities
- Propose actions in order to take advantages of the potential benefits identified for the national market
- Initiate the reflection of the national stakeholders acting in the biomedical technologies sector

ILNAS, supported by ANEC, are willing to provide an active contribution and to support future standardization activities and initiatives related to the biomedical technologies sector

Meet the persons interested in our approach

Creation of an advisory board

Propose a diagnostic to evaluate the standardization maturity of your entity

Provide answers to identified needs and demands

Creation of a national BiomedTech standardization forum

Consider your suggestions regarding standardization

Collection of comments and feedbacks to improve our report

Provide regular updates of the standards watch

**Thank you
for your attention**

ANEC

Agency for standardization and knowledge-based economy

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