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# nanoSTAIR: a new strategic proposal to impulse standardization in nanotechnology research

**JM López de Ipiña[1], O Salvi[2], B Hazebrouck[2], A Jovanovic[3], F Carre[4], A Saamanen[5], D Brouwer[6], M Schmitt[7], S Martin[8]**

[1] TECNALIA – Parque Tecnológico de Alava, 01510 Miñano/Spain
[2] EU-VRi - Willi-Bleicher-Straße 19, 70174 Stuttgart/Germany
[3] STEINBEIS Haus der Wirtschaft Willi-Bleicher-Strasse 19, 70174 Stuttgart/Germany
[4] INERIS - Rue Jacques Taffanel, 60550 Verneuil-en –Halatte/France
[5] FIOH - Topeliuksenkatu 41 a A, 00250 Helsinki/Finland
[6] TNO - Utrechtseweg 48, 3704 HE Zeist/The Netherlands
[7] DIN - Burggrafenstraße 6, 10787 Berlin/Germany
[8] CEN – CENELEC - Avenue Marnix 17, B-1000 Brussels/Belgium

E-mail: jesus.lopezdeipina@tecnalia.com

**Abstract**. Nanotechnology is considered one of the key technologies of the 21st century within Europe and a Key-Enabling Technology (KET) by Horizon 2020. Standardization has been identified in H2020 as one of the innovation-support measures by bridging the gap between research and the market, and helping the fast and easy transfer of research results to the European and international market. The development of new and improved standards requires high quality technical information, creating a fundamental interdependency between the standardization and research communities. In the frame of project nanoSTAIR (GA 319092), the present paper describes the European scenario on research and standardization in nanotechnology and presents a proposal of a European strategy (nanoSTAIR) to impulse direct "pipelines" between research and standardization. In addition, strategic actions focused on integration of standardization in the R&D projects, from the early stages of the design of a future business (Project Proposal), are also described.

## 1. The European context on standardization and research in nanotechnology

Nanotechnology has been identified as a Key-Enabling Technology (KET) in Horizon 2020 (H2020). It has rapidly promoted the development of a new generation of smart and innovative nano-enabled products and processes, creating an important growth potential for a large number of industry sectors. Nanotechnology offers substantial possibilities for improving the competitive position of the EU and for responding to key societal challenges. But ensuring nanotechnology is developed in a safe and responsible manner is a key objective.

The production of knowledge in nanotechnology is very intensive as a great amount of research projects is launched each year, both on national and European level [5]. The European Commission has identified the time between the end of a research project and the beginning of the valuable exploitation of these results from the industry — the so called "valley of death" — as one of the main obstacles for economic success. In this context, standardization has been recognized in H2020 as one of the innovation-support measures by bridging the gap between research and the market, and helping the fast and easy transfer of research results to the European and international market, providing interoperability between new and existing products, services and processes.

To support the safe development of nanotechnologies, risk management should become an integral part of the culture of the organizations involved in the supply chain, including regulatory support and risk governance. The Nanosafety Cluster published in 2013 a roadmap aims to provide an

understanding of where the European nanosafety should be at the end of H2020, introducing a strategic vision for future research on the safe use and safe applications of engineered nanomaterials during 2015-2025 [9] .

The document identifies the steps and achievements needed to accomplish objectives within this time frame, describing the current status and the research needs and priorities for the coming 10 years in four main thematic areas: 1) nanomaterial identification and classification; 2) nanomaterial exposure and transformation; 3) hazard mechanisms related to effects on human health and the environment; and 4) tools for the predictive risk assessment and management including databases and ontologies. The report recognizes that standardization is highly important in promoting the success of engineered nanomaterials and technologies, and when incorporating safety as a vital issue in the standardization process.

On June 2011, the European Commission adopted a Communication entitled "A strategic vision for European standards: Moving forward to enhance and accelerate the sustainable growth of the European economy by 2020", that places in focus the important role expected from standardization in supporting the Europe 2020 Strategy for smart, sustainable and inclusive growth [3]. The document identifies European standards as an important step for bringing research results to the market and for the validation of technologies. This is particularly important for nanotechnologies, because standards in this field can facilitate the introduction of new products and contribute to the public acceptance of these innovations.

In 2010, CEN accepted 'Mandate M/461 - Standardization Mandate to CEN, CENELEC and ETSI for standardizations activities regarding nanotechnologies and nanomaterials [2]. In 2013, CEN/TC 352 'Nanotechnologies' was involved together with CEN/TC 195 'Air filters for general air cleaning' and CEN/TC 137 ' Assessment of workplace exposure to chemical and biological agents' in developing several European deliverables under this Mandate.

**Table 1.** Key players in the European context on standardization and research in nanotechnology

| Research | Standardization | Industrial | Regulatory |
|---|---|---|---|
| ▪ Research projects and organizations: see CORDIS, NSC, OECD, databases<br>▪ Nanosafety cluster<br>▪ European Technology initiatives: ETPs, EIPs, PPP<br>▪ European, national and regional research funding agencies.<br>▪ ERA-NET on Nanosafety (SIINN)<br>▪ NMP NCP Network | ▪ European Standardisation Bodies (ESB): CEN, CENELEC, ETSI<br>▪ National Standardization Bodies (NSB): DIN, AENOR, AFNOR, etc<br>▪ International Standardization Organizations: ISO, OECD, … | ▪ Industry and industrial associations (NIA) | ▪ European Commission<br>▪ EC - Advisory Committees and Agencies: SCCP, SCHER, SCENIHR, EFSA, ECHA, …<br>▪ Project NANoREG |

According to Nanotechnology Industries Association (NIA), in the field of nanotechnology, the development of appropriate nomenclature and standards is still in its infancy, and fast progress is urgently required so as to avoid hampering the development and acceptance of nanotechnology-based innovation. So far over one hundred key vocabularies, as well as dozens of technical specifications and reports, have been produced. Nevertheless many more are needed and active industry participation in the standardizations process is of the utmost importance in ensuring the best possible market conditions for nanotechnologies.

The regulatory uncertainties are considered as one of the main challenges in bringing nanomaterials to market in Europe. The current debate, including on the lack of regulatory clarity and on the uncertainties surrounding the potential risks of nanotechnology and nanomaterials have had a negative effect on their development, uptake and exploitation in Europe and have been clearly identified as a major barrier to innovation based on these technologies. Standards play a role for regulatory compliance, in particular in areas where regulation requires a risk assessment and risk management

approach, compliance with which can be demonstrated by standards. In general, the application of standards, unlike legal texts, is voluntary. Standards can however become part of legislation, when their wording or content is taken up by legal texts (New Approach Directives and harmonized standards).

Scientific activities make a key contribution to the standardization process [5,10]. H2020 documents refer standardization as an important element to enhance the competitiveness of European industry by promoting the take-up and trade of novel technologies. Many calls for funding programs of RTD projects refer to standardization as a relevant requirement to be considered by the project. This is due to the advantages that standardization provides the project on issues such as interoperability, dissemination of results and supports the market introduction.

According to a study presented by CEN and CENELEC [12], one in eight FP7 calls made explicit reference to standardization, and that projects funded under these calls were almost three times more likely to make use of standards than projects funded through calls that did not refer to standardization. In brief, 43% of all FP6 and FP7 projects addressing standardization in some way: 39% of projects used standards as an input, 12% proposed new or revised standards as an output, and 8% contributed to the development of new or revised standards. The same study showed nearly three-quarters (73%) of FP6 and FP7 project coordinators who included standards in their previous projects said that they would be willing to address standardization again. The FP7 priority areas estimated to have the highest share of projects addressing standardization were Security (75%), Transport (including aeronautics) (66%), ICT (62%) and Energy (60%).

**Table 2.** Fifteen most relevant standardization items identified by the nanoSTAIR survey [6]

| Num | Standardization item |
|---|---|
| 1 | Protocols for the characterization of manufactured nanoparticles from aerosols and from environmental sources, including sampling, sample stabilization, agglomeration, aggregation, etc. |
| 2 | Repeatability, reproducibility and intercomparability of test methods. |
| 3 | Guide to the identification and definition of measurands required for characterizing, evaluating functional properties and performance etc., of materials and devices at the nanoscale. |
| 4 | Guidance on nano-material characterization prior to, or in association with toxicity testing. |
| 5 | Guidance on dosimetry and exposure determination in occupational settings relevant to manufactured nanomaterials. |
| 6 | Guidance on safe handling of manufactured nanoparticles and other manufactured nanoscale entities (including selection of Personal Protective Equipment). |
| 7 | Inter-Laboratory Comparisons and validated methods/techniques for measurement/control of quality, process, etc. |
| 8 | Development of Reference Materials and Certified Reference Materials dedicated to existing and new techniques, particularly for challenging and checking the functioning/calibration of nanoparticle measurement and analysis equipment. |
| 9 | Related metrology (instrumentation and techniques) for measurement and characterization of nanoparticles and other nano-objects. |
| 10 | Guidance on sample preparation for toxicity testing, toxicokinetic and ecotoxicokinetic (air, water, soil) studies on nanoparticles and other nanoscale entities. |
| 11 | Guide to the management of waste and the disposal of nanomaterials. |
| 12 | Guide to performance measurement of nanoscale materials and devices. |
| 13 | Guidance on integrated (toxicity) testing strategies (ITS) and integrated risk assessment. |
| 14 | Protocols for evaluating the effects of short and long term dermal, nasal, oral and pulmonary exposure to, elimination of, and fate determination for nanoparticles and other nanoscale entities. |
| 15 | Guidance on detection and identification of nanoparticles and other nanoscale entities (in all media types, including waste streams from manufacturing and manufacturing discharges). |

The development of new and improved standards requires high quality technical information. This creates a fundamental interdependency between the standardization and research communities. Consequently the need of direct “pipelines” to connect research to standardization has been widely recognized and promoted by European Commission, European Standardization System and other interested parties, in order to use standards to drive markets and build consumer confidence.

Integration of European research and standardization is a recurring topic, at least in the last two European research programs (FP6, FP7). In fact, agents of European Standardization System (ESS) and European Innovation System (EIS) have been involved in projects related to that topic in FP6 and FP7 programmes (e.g. FP6 -INTEREST, FP -7 nanoSTAIR, BRIDGIT).

The project nanoSTAIR carried out a survey to clearly identify the needs of European stakeholder for new standards in nanotechnology, to bridge the gap between the research objectives and the standardization needs, by facilitating the process of clustering [6]. Research and development stakeholder group was the biggest interested part, representing 76% of the answers. The table 2 summarizes the fifteen most relevant standardization items identified by the survey.

There are some important barriers that inhibit participation of research community in standardization. The list can be synthesized into three main categories [4]: 1) Resources required for participation (money, time, personnel, etc.); 2) Standardization process (length, flexibility, IPR rules, integration of input, etc.); 3) Awareness and visibility of standards and standardization (awareness of benefits, links to SSBs, helpdesks, etc). In this regard, table 3 groups all the barriers identified by literature sources consulted by project nanoSTAIR [1,4,7,8,9,11] .

**Table 3.**Barriers identified in the literature consulted by nanoSTAIR, classified in the three main categories as established by project INTEREST [7,8]

| Barriers and literature sources | Resources required for participation | Standardization Process | Awareness and recognition of standardization |
|---|---|---|---|
| Project INTEREST (FP6) (2006) | ▪ "My expenses are not covered by my organization or by third parties." (The most important barrier by far). | ▪ "The standardization process is not flexible and fast enough." | ▪ "Standardization activities do not have a positive impact on the evaluation of my research."<br>▪ "My expertise is not relevant in the standard-setting process." |
| NMP Expert Advisory Group (2012) | ▪ Funding for pre- and co-normative research, although relatively small, is extremely difficult to find. | ▪ Timescale of research projects often not aligned with standardization timescale. | ▪ Researchers and standardizers often operate in different circles<br>▪ Lack of knowledge on the potential contribution of the projects towards the development of new standards or to the improvement of existing standards.<br>▪ Little recognition and enhancement of a research career |
| NSC Strategy (2013) | ▪ Lack of resources to invest time for standardization activities | | ▪ Lack of awareness among researchers of what is going on in standardization<br>▪ Lack of incentives for researchers to invest time and efforts. |
| CEN-CENELEC (2013) | ▪ Lack of funding to take forward the proposed standards development work<br>▪ Lack of resources to provide inputs to the development process | ▪ Inherent complexity of the standardization world<br>▪ Non-alignment between the project and standardization 'timetables'<br>▪ Uncertainty surrounding the decision-making process<br>▪ Difficulties gaining access to Standardization Bodies and their TCs | ▪ Competition from other competing proposals or ideas in similar or related areas<br>▪ Difficulty in gaining acceptance of the inputs provided<br>▪ Difficulties generating industrial support for new standards |
| CEN-CENELEC Project BRIDGIT (2014) | ▪ Resource commitment required to participate in standardization activities is too high for researchers<br>▪ Standards bodies lack resources | ▪ Lack of comprehension of the world of standards<br>▪ Operation of the standardization process | ▪ Mutual irrelevance of standardization and research<br>▪ It is not clear which research is relevant<br>▪ Lack of recognition of researchers professional contribution |

In this context, the project FP7 nanoSTAIR - finished in 2014 – carried out research to build a sustainable process, a platform and a set of advanced tools (services) in the field of nanotechnologies, to support the transfer of knowledge gained through research to standards and standardization deliverables, in the framework of the STAIR approach promoted by CEN-CENELEC [1]. Recently a

consortium consisting of 10 NSBs and CEN and CENELEC also completed the project BRIDGIT, funded by the EC and EFTA, aimed to "bridge the gap" between standardization, research and innovation.

## 2. nanoSTAIR: contributing to impulse standardization in research

Summarising of all information sources consulted by nanoSTAIR [7], it can be suggested that perception of EIS agents on the interest of standardization and its importance in research projects, closely depends on several factors: 1) Typology of research agent (e.g. university, research institute, technology centre, RDI unit of a company, other stakeholders); 2) Research area concerned (e.g. fundamental research, technology development, demonstration); 3) Existence of a previous experience or established relationship between EIS and ESS agents (e.g. agent's participation in technical standardization committees (TC), working with ESS in previous research projects, etc.); 4) Technology Readiness Level (TRL) assigned to research project; 5) Life cycle stage of project concerned (Call for proposals, preparation of the proposal, evaluation process, negotiation phase, implementation phase, stage of completion and exploitation of results); 6) IPR issues involved in the project and 7) European country, relationships between research community and NSB.

nanoSTAIR strategy [7] has been designed as a tool to impulse standardization in research, either at national or European level. The strategic approach is based on the systematic analysis of the barriers that have been identified (Table 3) and of the possible ways to overcome these barriers, involving all relevant actors and identifying the possible benefits for them.

**Table 4.** Number of strategic actions to be deployed by nanoSTAIR strategy, classified by typology of barrier and strategic objective concerned [7].

| nanoSTAIR Strategic Objectives | | Barriers | | | | |
|---|---|---|---|---|---|---|
| Main objective | 2nd Level | RA[1] | SP[2] | ARS[3] | Total | |
| SO1.- Ensure that nanotechnology standardization is visualized as a demand to be satisfied by researchers, research organizations and research projects | SO1.1.- Reinforce visibility of nanotechnology standardization in research projects | 4 | 0 | 9 | 13 | 16 |
| | SO1.2.- Foster a culture of implementation of research results in standardization deliverables | 0 | 2 | 1 | 3 | |
| SO2.- Provide support to research projects, from the European Standardization System (ESS). | SO2.1.- Facilitate contact between research projects and standardization organizations | 1 | 2 | 4 | 7 | 15 |
| | SO2.2.- Provide practical tools to solve standardization issues in research projects | 0 | 2 | 4 | 6 | |
| | SO2.3.- Develop a networking with a view of exchanging experiences and best practices among members of ESS | 0 | 0 | 2 | 2 | |
| SO3.- Provide support to ESS, from the research community | SO3.1Facilitate contact between standardization and research community | 0 | 0 | 2 | 2 | 2 |
| SO4.- Establish and deploy a sustainable platform of services - nanoSTAIR - to facilitate the interaction between research and standardization | SO4.1.- Provide research projects, advanced services to properly manage standardization issues | 0 | 0 | 19 | 19 | 20 |
| | SO4.2.- Ensure sustainability of nanoStair platform after project completion | 1 | 0 | 0 | 1 | |
| | Total | 6 | 6 | 41 | 53 | 53 |

[1] RA: Resources available
[2] SP: Standardization process
[3] ARS: Awareness and recognition of standardization

The strategy rests on five pillars: 1) Strategic focus on the research project throughout its life cycle, as a key element for bridging research (EIS) and standardization (ESS); 2) Visualization of

standardization as a need to be satisfied by research projects; 3) Proximity and accessibility to standardization resources. The strategic approach pivots on NSB, due to its proximity and ease of interaction with project partners as well as their ability to provide resources to the project in the field of standardization; 4) Synergistic approach to standardization and strategic actions aimed at coordinating European and national efforts – ESS and National Standardization System (NSS) - to maximize impact and 5) Development of a private platform of services - nanoSTAIR - to facilitate integration between research and standardization.

The project identified four strategic objectives, aimed at bridging barriers and facilitate connections between research and standardization, and a set of targeted strategic activities for deployment. The table 4 and figure 1 summarize nanoSTAIR strategy and show that all types of barriers described in table 3 have been considered by the strategic approach. The total number of strategic actions considered is 53. The deployment of these actions may take place at European level only, national level or in both areas.

The largest number of actions concerns the Strategic Objective 4 (SO4: Deploying nanoSTAIR platform), followed in short order by objectives 1 and 2. These last two objectives are closely related to the satisfaction of the needs of researchers, research organizations and research projects, and both account for more than half of the strategic actions proposed by nanoSTAIR (57%).

By type of barrier concerned, the largest number of actions (78%) is directed towards the awareness and recognition of standardization, as a strategic pillar to establish direct pipelines between research and standardization. Actions to provide resources and actions to improve the standardization process represent the remaining 22%, equally distributed (11% each).

The document containing nanoSTAIR strategy will soon be available for download at the project website (www.nanostair.eu-vri.eu/).

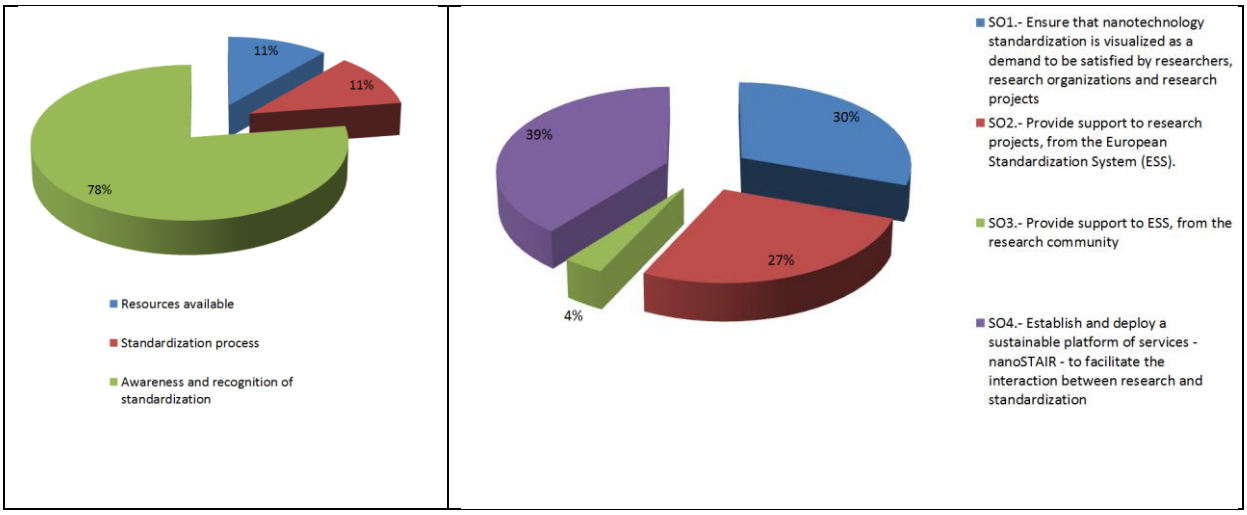


**Figure 1.** Distribution of nanoSTAIR strategic actions according to the type of barrier (Top) and the strategic objective concerned (Bottom) [7,8].

## 3. Integrating standardization in research projects from the early stages

Integrating standards and standardization in project proposals can amplify the impact of projects, facilitate the dissemination and exploitation of research results, and ensure a better evaluation. Integration of standardization in research project involves, at least, two basic actions: 1) Consider existing standards and standardization deliverables as a part of the project´s state of the art; 2) Use standards and standardization deliverables as an effective means to disseminate and exploit the project results and facilitate market access. nanoSTAIR proposes a simple procedure in five steps [8] (Figure 2).

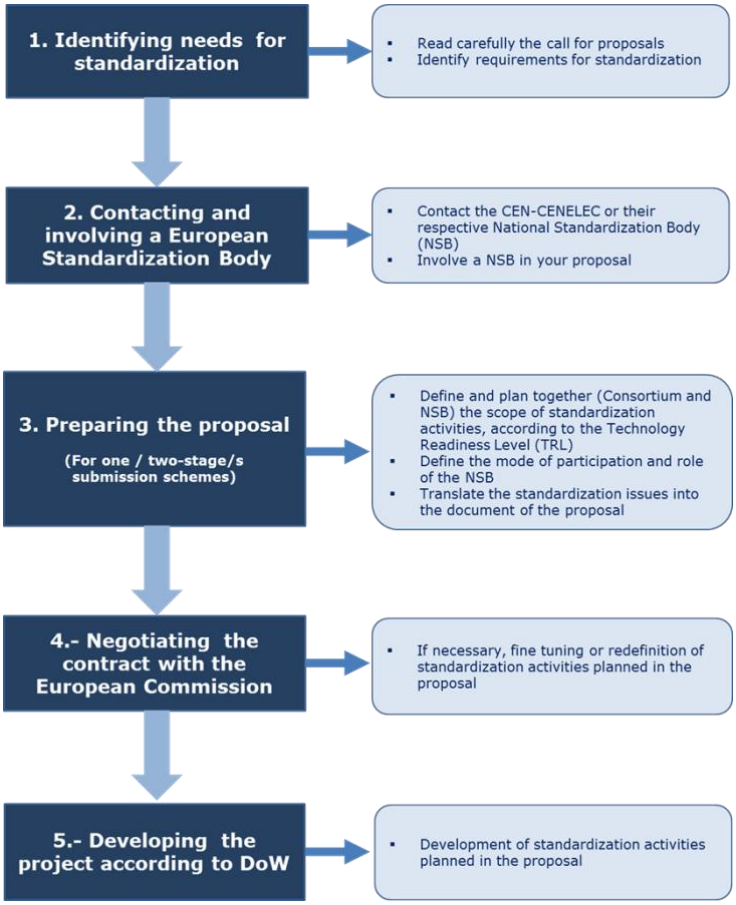


**Figure 2.** Basic procedure to integrate standardization in the research project [8]

Depending on the Technology Readiness Level (TRL) considered by the proposal, a different set of standardization activities can be defined. As an example, in Table 5, a proposal to select standardization issues according to the TRL is presented [8]. As can be seen, when the TRL level increases, the complexity of recommended standardization activities grows in parallel.

Finally, notice that CEN and CENELEC cannot become formal partner in European funded research projects, delegating this participation in their national representatives (NSB). Consequently the most effective way to support the integration of standardization in a research project is to involve a NSB.

From a higher to a lower degree of involvement, the NSB can become: 1) A partner of the consortium; 2) A subcontractor of a consortium partner, exclusively for project standardization activities; 3) A member of the project International Advisory Board or Steering Committee; 4) An organization that supports the project by providing a Letter of Intent (LOI).In this sense, to facilitate the national interaction between the research and standardization communities, most of CEN and CENELEC members have appointed a dedicated national contact point (DNCP). For members without a DNCP, you can use their generic e-mail address.

**Table 5.** Proposal for standardization activities, according to the project's TRL [8]

| | TRL | Description | Minimum standardization activities expected or recommended | Types of proposed standardization documents |
|---|---|---|---|---|
| Basic & applied research | 1 | Basic principles observed and reported | 1.- Identification of published or under development applicable standards. | |
| | 2 | Technology concept and/or application formulated | | |
| | 3 | Analytical and experimental proof of concept established | 2.- Identification of new standardization fields. | ▪ Terminology |
| Demonstration in lab /Simulation/real | 4 | Laboratory validation of component or process | Previous activities and: | ▪ Testing methods |
| | 5 | Validation of component or process in simulated environment | 3.- Collaboration with existing standardization Technical Committees. | ▪ Characterization<br>▪ Best practices |
| | 6 | Subsystem model or prototype demonstrated in relevant environment | 4.- Technical proposals for new or revised standardization documents. | ▪ Specifications for products, services, processes, etc |
| Implementation, industrialization, commercializatio | 7 | Integrated pilot system demonstrated in operational environment | Previous activities and: | |
| | 8 | Actual system completed and qualified through test and demonstration | 5.- Participation and leadership in the elaboration of new or revised standardization documents. | |
| | 9 | System ready for full scale deployment, end-use operation | | |

## 4. Conclusions

Standardization is a powerful tool to transform the innovation produced from R&D projects into marketable tangible results; in future business. Especially when it comes to innovation, standardization is basic to provide confidence to consumers on new products / services and to ensure the fulfilment of applicable regulations.

The strategic approach formulated by project nanoSTAIR is based on the systematic analysis of the barriers between research and standardization, and of the possible ways to overcome them. It defines four strategic objectives and 53 strategic actions for deployment during the period 2014-2020 that may be used to promote "direct pipelines" between research and standardization at European level only, national level or in both areas.

The strategic deployment is addressed to visualize standardization as a demand to be satisfied by researchers, research organizations and research projects, and to establish effective bidirectional connections to support research and standardization communities, including the creation and deployment a sustainable platform of services - nanoSTAIR - to facilitate the interaction between them.

Within the approach nanoSTAIR a proactive strategy, considering standardization since the early stages of the design of our business (Project Proposal), is key to accelerating the adoption and entry into the market of new products / services and avoid potential trade barriers.

## References

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