STANDARDS DEVELOPMENT IN LIFE SCIENCES

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Standards Development in Life Sciences

An introduction of standards and modern approaches on how to accomplish them

A conjoint work from IEEE EMB Standards Committee and IEEE Life Sciences Technical Community

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Innovation Through Standards: See How it is Done and Get Involved!

By Carole C. Carey

Emerging technologies in medicine, biology, life sciences and engineering are focusing more than ever on innovative products in delivering safe effective medical devices, novel therapeutic treatments, and efficiency of health care systems around the world. The aim is for patients to have early access to innovative devices as well as reduction in costs of medical products.

Standards Do Matter

Standards are published formal documents that establish uniform specifications and procedures to ensure quality, compatibility and reliability of materials, products, methods and/or services. They support and facilitate interoperability between devices made by different producers. Standards are often derived from innovative technology and are based on the consensus participation of multidimensional views; manufacturers, researchers, policy makers, interest groups, and users. Effective approaches are required. Standards can help reduce the timelines from scientific research discoveries to clinical practice to product technology commercialization. One proven approach is the recognition and consideration of incorporating the use of standards in every stage of the translation roadmap from 'bench to bedside'. Conformance to high quality standards provides assurance to stakeholders on the quality of products and consistency of processes and production methods.

We are witnessing a rapid increase of innovative products and wearables from emerging technologies in both the consumer and healthcare space, such as artificial intelligence, 3D-based bioprinting, brain computer/machine interface, medical robotics, and blockchain for life sciences among others. Standards are lagging behind. The development of standards needs to catch up with technology innovations. Collaboration among standards developers around the world should expand and intensify.

Regulatory Challenge and Opportunity

Medical devices are highly regulated products. One of the challenges that manufacturers face, particularly multinational firms, is overcoming complex government regulatory review of new devices. A lengthy market approval process can impede innovation and delay the availability of better health and healthcare systems. Regulatory bodies across international jurisdictions recognize that established industry consensus standards help simplify the process of designing, developing, testing and manufacturing new technologies. Regulators support the use of harmonized standards as one of the regulatory tools that augment the supervision and management of medical products. The harmonized process, allows innovative devices to reach patients quicker, is considerably streamlined. Moreover, the cooperation between government and regulated industry greatly reduces the regulatory burdens on both sides.

IEEE Standards Development: Guiding Principles

International standards are generally developed through a voluntary consensus process that brings together volunteers and subject matter experts with an interest in the standards' topics to be considered. One purpose of establishing standards is in response to technical, safety, performance, regulatory, societal and market needs in order to serve the public good. Most standards are generally made available to the public. Through an accredited consensus process, standards setting bodies or standards development organizations (SDOs) like IEEE, IEC, ISO and others manage and facilitate the development of standards. Although the goals of SDOs are essentially the same, each SDO applies its own set of rules, terminology, processes, policies, and guidelines. They help ensure the integrity of the standards development process.

The IEEE organizational unit that oversees the standards development process is the IEEE Standards Association (IEEE-SA). The IEEE-SA Standards Board (IEEE-SASB) and its Committees provide the policies and guidelines for the development of individual and entity-driven standards in order to ensure a fair and equitable process. These Committees include the New Standards Review Committee (NesCom), Standards Review Committee (RevCom), Procedures Committee (ProCom), Audit Committee (AudCom), and Patent Committee (PatCom). IEEE-SA adheres to the Open Stand paradigm and supports the principles and requirements of WTO (*World Trade Organization's Decision on Principles for the Development of International Standards, Guides and Recommendations*). It should be noted that the IEEE-SASB does not develop the standards. Collaborative teams or standards working groups (WGs) are formed to develop standards. IEEE-SA staff provides guidance and operational support.

Participation in WGs is also guided by five basic principles.

1. **Openness**: Participation in IEEE standards development is open to all interested parties, IEEE members or non-IEEE members alike.

2. **Due Process**: Highly visible operating procedures are followed.
3. **Balance**: No one party has an overwhelming influence in the ballot group.
4. **Consensus**: Resolving differences of opinion and a clearly defined percentage of those in a balloting group vote to approve a draft of the standard.
5. **Right of Appeal**: Anyone may appeal a standards development decision at any point, before or after a standard has been approved.
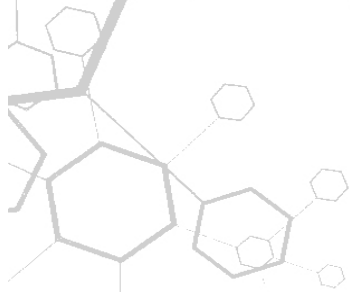
It All Starts with An Idea or Concept

A standardization project usually gets under way when a person or a group of people with similar interest identifies a specific topic in need of standardization. The idea or concept can be broad or very specific. An example is standardization of common terms, definitions, or symbols. Standards projects can be about technical characteristics, performance, and safety requirements associated with devices, equipment, and systems. They can also be about recommendations reflecting current state-of-the-art in the application of engineering principles. There are many more examples.

In IEEE, the term Standards encompasses three types of projects and/or documents: Standards ("shall" contains mandatory requirements), Recommended Practice ("should" outlines preferred procedures), or Guide ("may" offers suggestions for working with a technology). When deciding on starting a standards project, the potential working group should take into consideration the following criteria: (1) Broad market potential, (2) Technical feasibility, (3) Readiness for standardization, (4) Distinct identity or substantial technical merit when compared to other standards, and (5) Adequate participation, enough participants to step forward to develop the standard.

Figure 1. Six stages Standards Development Lifecycle

1. Initiating the Project. Project authorization request (PAR) is a small structured document that defines the scope, purpose and need for a standard. It requires NesCom (New Standards Committee) and the IEEE Standards Association Standards Board (SASB) approval. An IEEE standard project also needs a Standards Committee, formerly known as the Sponsor) that assumes the responsibility for a particular standards idea. They provide technical oversight, including the organization of the standards development team and its activities, from inception to completion. Standards Committees are typically from the IEEE technical Societies and Councils. An IEEE-SASB approved PAR marks the official start of the standards project. *This is the time to submit a PAR through myProject (a web-based tool that facilitates the IEEE standards development process)!*

2. Mobilizing the Working Group. "Working Group" is term IEEE uses to refer to the collaborative team that actively develops a standard, recommended practice or guide. Other SDOs may refer to their groups using different terms or may follow slightly different processes. Working Groups are comprised of individuals and/or entities (people, companies, organizations, non-profits, government agencies) who volunteer to support the development of standards. The WG Chair calls for participation. *This is a good time to sign up and join the "Kick-off" meeting and attend future meetings!*

3. Drafting the Standard. Under the leadership and guidance of the WG Chair, who also acts as the point of contact for technical questions, the WG makes technical decisions in the process of developing the standard. The WG's first milestone is completion of the first mature draft in order to move the project for Standards Committee approval, the ballot process and ultimately IEEE-SASB approval. *This is the time to make contributions to the standard draft development and help the WG move forward!*

4. Balloting the Standard. The goal in balloting is to gain the greatest consensus and balance with no dominance by any one group of interest or company. Balloting process starts when the Standards Committee determines the draft of the full standard is stable. The Standards Committee Chair, WG Chair or designated person can initiate the invitation to form the balloting group (persons interested in the standard). Anyone can contribute comments through the Public Review process. However, only votes from eligible members of the balloting group count toward approval. *This is the time to enroll and join the ballot pool and participate in the consensus ballot!*

5. Gaining Final Approval. The completed standard and supporting materials are submitted to RevCom (Review Committee) to ensure the WG followed all procedures and guiding principles in drafting and balloting the standard. All negative comments must be resolved and require ballot recirculation(s). Similar to the PAR, the completed standard will ultimately be presented to IEEE-SASB for approval/disapproval. IEEE-SA professional editor reviews multiple drafts during development. After IEEE-SASB approval, the editor prepares the final text for publication. *The primary task is completed once the standard is approved and published!*

6. Maintaining the Standard. An IEEE standard is valid for 10 years from the date of IEEE-SASB approval. Amendments and Corrigenda (corrections of technical errors) can be developed and balloted within the 10-year validity rule. If the standard becomes outdated, a Revision can be initiated. After 10 years, one of two actions can occur: revision or withdrawal. *It would be beneficial to stay up-to-date on technology developments, new information from research and product field experience.*

Standards help ensure consumer safety and interoperability across devices. Participation in developing global, consensus standards in an open platform encourages innovation, drives competition among product designers and developers, and promotes international trade. *Please, get involved!*

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Standardization of Three Dimensional (3D) and Four-Dimensional (4D) Based Medical Application

By Young Lae Moon, Dae Ok Kim, Wonbong Lim

Standardization of medical 3D and 4D Application has not been pioneered.

Additive manufacturing, otherwise known as medical 3D, is driving major innovations in many areas, such as manufacturing, engineering, art, education and medicine. Especially, the medical field is greatly becoming interested in this technology with the ability to create solutions specifically tailored towards the patient. From the creation of 3D models that help surgeons plan operations, to the fabrication of patient-specific titanium implants, 3D printing is already changing the traditional medical industry. In our Working group, sponsored by IEEE Engineering in Medicine and Biology Society (EMBS) as a primary sponsor for 3D Based Medical Application Working Group (EMB/Stds Com/3333.2) with the Computer Society as joint sponsor, practical applications of medical 3D have been suggested the demand for technical standards for clinical educational utilities.

Medical imaging and modeling procedures for solid organ 3D printing

Medical images from hospitals consist of a two-dimensional (2D) dataset and provide human body information as a slice, however the human body has a three-dimensional (3D) morphology. If we reproduce a 3D morphology via simulations, we might be able to obtain more information about the body as well as contribute in the clinical environment to both better treatment and surgical outcomes. The objective for solid organ 3D printing is to generate 3D medical data from 2D images. Although doctors spend a great deal of time and effort in this process, the resultant 3D data are usually different in each institute. A standardized procedure provides standard, simple and accurate 3D data for solid 3D printing.

Figure 1. The Procedure for hard and soft tissue 3D printing

The procedure for hard and soft tissue 3D printing

Standardization in hard and soft tissue printing involves the use of medical scanning devices to acquire physical data models with
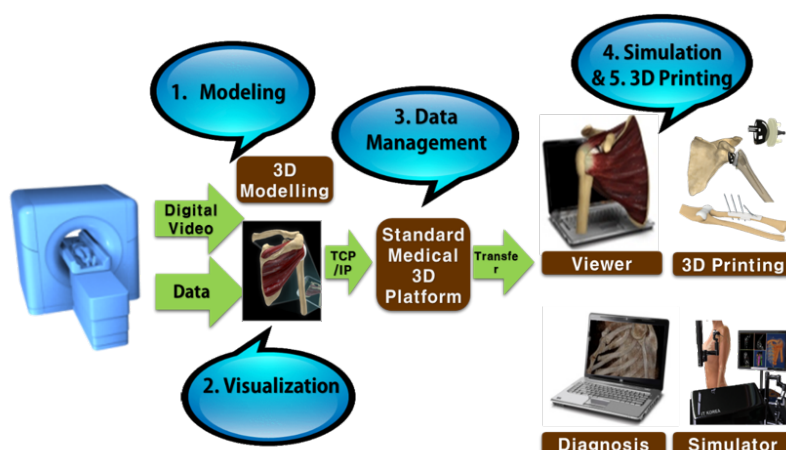
density and size characteristics which are necessary to develop comparative analysis data. In order to achieve an accurate segmentation, it is necessary to apply certain segmentation algorithms, including processing step, such as extracting bone features with image enhancement and density selection. The standard for hard and soft tissue 3D printing defines a procedure that increases the precision of 3D printing model output of hard or soft tissues in medical images. In addition, medical imaging and modeling procedures for hard and soft tissue 3D printing will include the following features: 1) Modeling for image enhancement, 2) Visualization in medical image, 3) Data management, 4) Simulation and 5) 3D printing (Fig.1).

Standardization of personalized artificial joint implant 3D model design

The goal of medical 3D printing in the orthopedic field is to reproduce the normal biomedical functions of missing bones. It is necessary to output and apply the artificial joint replacement as the presently feasible intermediate step. This standard is to apply the output to the operation by individually optimizing the shape of the implants of the lost joint based on the rotation data of the positional rotation of the mirrored motion in the normal joint. The use of CAD based on medical image is essential, and a designing technique that minimizes the modeling error is needed. Therefore, definition of optimal design elements for medical 3D printing and development of technical standards based on the analysis of medical elements of artificial joint output are required for analysis of patients' three-dimensional model data, artificial joint template and other technical factors. In order to maximize the patients and physicians' satisfaction with implant surgery, the accuracy of artificial prosthesis placement is important and surgical guide model design techniques are required to minimize errors.

Standard for in vivo evaluation of three-dimensional printed polymeric scaffolds in bone defects

The standard specifies the in vivo experimentation required for the biological assessment of three-dimensional (3D bio-printed polymeric scaffolds intended for the use in bone regeneration. 2D bio-printed scaffolds are gaining increasing attention, and animal experiments are fundamental in assessing their performance prior to potential clinical use. This international standard can be applied to the preclinical assessment such as animal experiments to evaluate the in vivo performance of 3D bio-printed porous polymeric scaffolds.

More recently, the 3D medical applications working group (P3333.2 WG) added 5 project authorization requests (PARs). The approved PARs are: "Standard for Soft Tissue Modeling for Medical 3D Printing," "Standard for Hard Tissue Modeling for 3D Printing," "Standard for Surgical Guide Design Modeling for Medical 3D Printing," "Standard for Artificial Joint Implant Design Modeling for Medical 3D Printing," and "Standard for In Vivo Evaluation of 3D Printed Polymeric scaffolds in bone defects." The resulting family of standards under IEEE P3333.2.5 (Standard for Bio-CAD file Format for Medical Three-Dimensional (3D) Printing) will create a substantial basis for improved medical diagnoses, surgical simulations, implant design, tissue engineering and virtual endoscopy, and personalized medical services.

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On Brain-Computer Interface Standards

By Luigi Bianchi

Brain-Computer Interfaces (BCI) allow people to interact with the environment for either communicating or controlling external devices without using the natural pathways of nerves and muscles [1]. By inducing endogenously or exogenously recognizable brain states, a user intention can be deduced by a special machine that can then drive an external peripheral.

Several different protocols have been proposed over the years, and several brain signals have been analyzed such as EEG, MEG, ECoG, fNIRS and fMRI.

BCI constitutes a highly multidisciplinary research field that has gained great interest in the last two decades, in which several research areas are involved such as engineering, computer science, robotics, neurology, neurophysiology, psychology and rehabilitation. Moreover, the experts must interact not only among themselves but also with patients, health professionals and medical doctors to design or tune a system in the most efficient way. This richness of expertise, however, has some drawbacks because different vocabularies and points of view are used to deal with the same model or BCI system element, and this can easily lead to misunderstandings. Since the early days, it was clear that the large variety of BCI systems could generate confusion: for this reason, in 2003, Mason et al [2] proposed a general static (e.g. no timing issues among modules were dealt) functional model, which

is illustrated in Fig. 1: the two relevant main components are the Transducer and the Control Interface. The transducer, in short, is responsible of detecting brain states and its output (a logical symbol, LS, which is the classifier output in general has no semantic meaning) constitutes the input for the control interface, which is responsible of encoding sequences of LSs into a Semantic Symbol SS such as a spelling device that converts classifier's outputs into a character of the English alphabet.

However, even if this functional model were widely adopted, how can we measure BCI performances? Typically, computer scientists are more interested at increasing brain states classification accuracy whereas Amyotrophic Lateral Sclerosis (ALS) patients are usually demanding to maximize their communication speed. Even if the two ways of expressing the performances of BCIs seem comparable, they
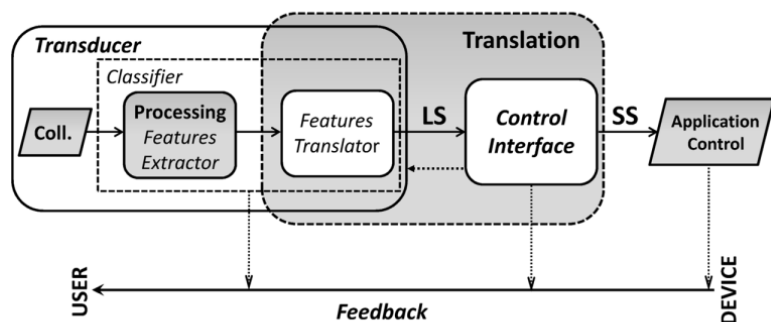

Fig. 1 – Mason's functional model of a Brain- Computer Interface

are actually not: in the first case only the identification of brain patterns is involved, that occurs at the output of the transducer, while in the second case also the control interface play a relevant role (e.g. the choice of the used

alphabet) that affects the performances of a system. This simple fact could make it difficult, if not impossible, to compare different systems and is caused by the lack of standardized procedures.

In addition, clear and widely accepted definitions of simple characteristics such as "trial", "session", "run", "real-time", are missing, which very often differ among research laboratories, manufacturers and the available frameworks, making the description of a system confusing.

In 2008, Quitadamo et al. [3] extended Mason's model that evolved from static to dynamic, thus dealing with timing issues and synchronization among the various elements, by means of a detailed description made in Unified Modeling Language (UML). In this work she demonstrated that it could be successfully applied to five different commonly used BCI protocols: P300, SSVEP, Motor Imagery, Slow Cortical Potentials and fMRI mental tasks. The great advantage of such implementation was that all the systems shared the same terminology and metrics and that it could be possible to unify their description, making it easy to compare and describe different systems. However, even if several BCI system frameworks were made available over the years, none of them but [4] fully adopted it, making it virtually impossible to share resources among different implementations and very often to compare the performances of the various systems.

As a consequence of all the different visions of what a BCI is, it seems impossible today to imagine converging towards common definitions and methods which allows a painless sharing of resources. The scenery is complex, with different models, methods and frameworks and consequently different file formats that make the cooperation among different laboratories very difficult.

Today the existence of BCI standards is mandatory and their adoption cannot be delayed anymore. This process, however, should be implemented smoothly in order to minimize the effort of making standard compliant to the actually available systems and to maximize the perception adhering to them will provide great advantages to patients, users, manufacturers and the scientific community.

The clear starting point of the standardization process is the definition and adoption of a common BCI functional model that will then open the way to the definition of file formats and tools for designing, describing, optimizing, evaluating, comparing and tuning systems that could be shared among caregivers, health professionals, researchers and engineers. IEEE Standards Association and Brain-Computer Interface Society can clearly play a fundamental role to achieve this goal. Previous experiences demonstrated that it is possible to share a common BCI model and terminology across a wide range of BCIs providing the aforementioned advantages.

A roadmap has been also proposed in [5] showing that relevant benefits can be easily obtained with little effort, even if limited to off-line analysis, systems configuration and in general non real-time BCI behavior. This last, which requires a relevant effort to adapt existing systems to a common dynamic implementation of a BCI, could be however addressed in a successive phase.

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