Doesn’t Everyone Love Legos?

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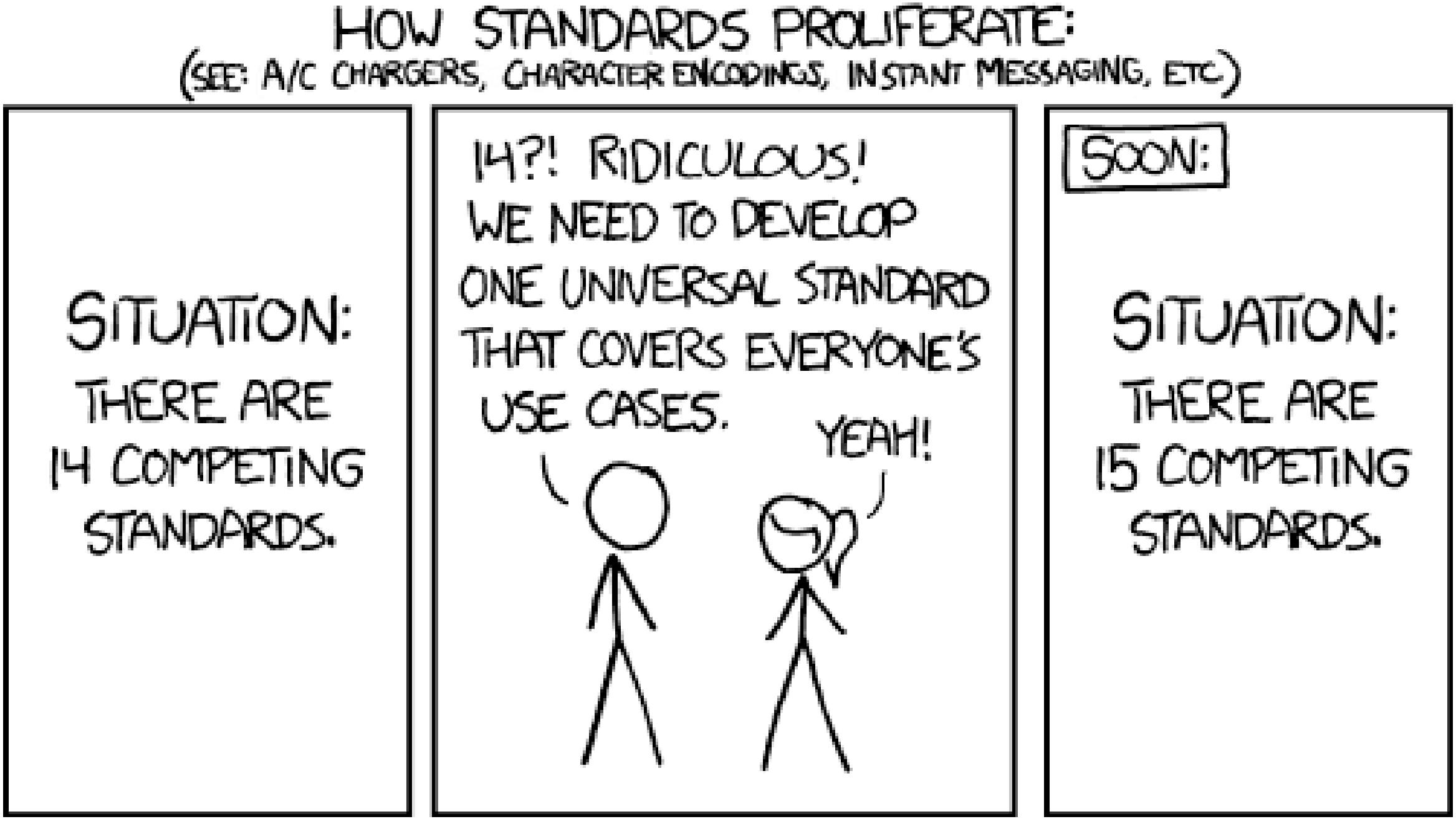
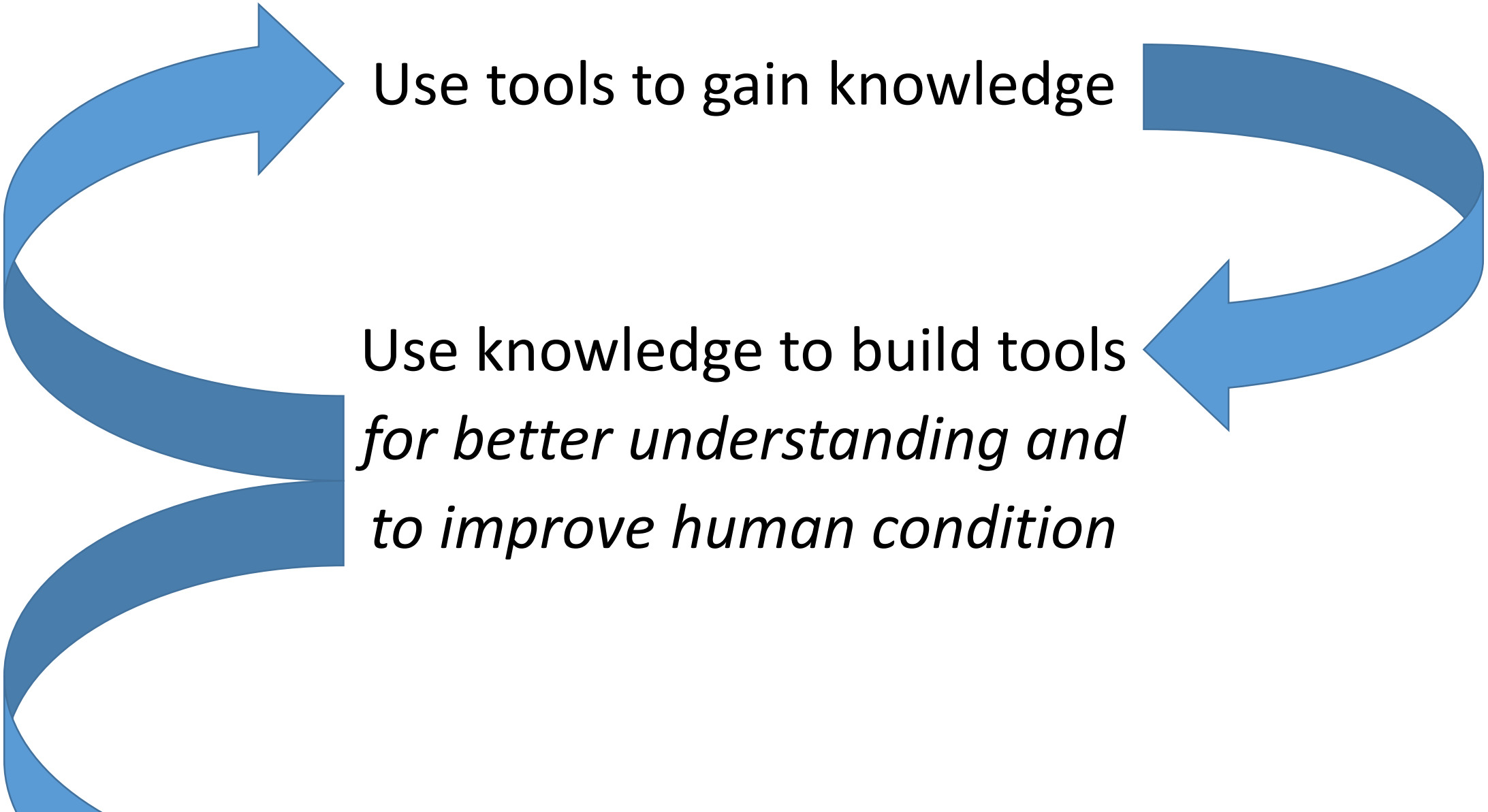
National Institutes of Health



http://xkcd.com/927/

Nomenclature

STANDARD	ISO, IEC, IEEE, ASTM, etc.	
convention	modularity	everyone uses Omnetics for research everyone uses Bal Seal for clinical
	interoperability	Neuroshare, Open Science Framework
	consensus	30 kS/s at 12 bits/S to reconstruct an AP
chaos	perpetual reinvention of the wheel	


Use tools to gain knowledge
Use knowledge to build tools
for better understanding and
to improve human condition

Why should scientists care?

Cost

- effort detracts from ability to do more research
- delayed gratification

Benefit

- cheaper, more interchangeable research tools
- focus energy on research, not reinvention of the wheel

Why engineers shouldn’t be terrified

Standardization

- Convention can satisfy most of today’s needs
- Formality only where necessary

Value

- If the parameters satisfy >50% of the community, everyone wins
- Facilitates regulatory pathway

We need to take action

Brain-Computer Interface Devices for Patients with Paralysis and Amputation: A Meeting Report

Bowsher K, Civillico EF, Collinger J, Conteras-Vidal JL, Denison T, Donoghue J, French J, Getzoff N, Hochberg LR, Hoffmann M, Judy J, Kleitman N, Knaack G, Krauthamer V, Ludwig K, Moynahan M, Pancrazio JJ, Peckham PH, Pena C, Pinto V, Ryan T, Saha D, Scharen H, Shermer S, Skodacek K, Takmakov P, Tyler D, Vasudevan S, Wachrathit K, Weber D, Welle CG, Ye M

Abstract

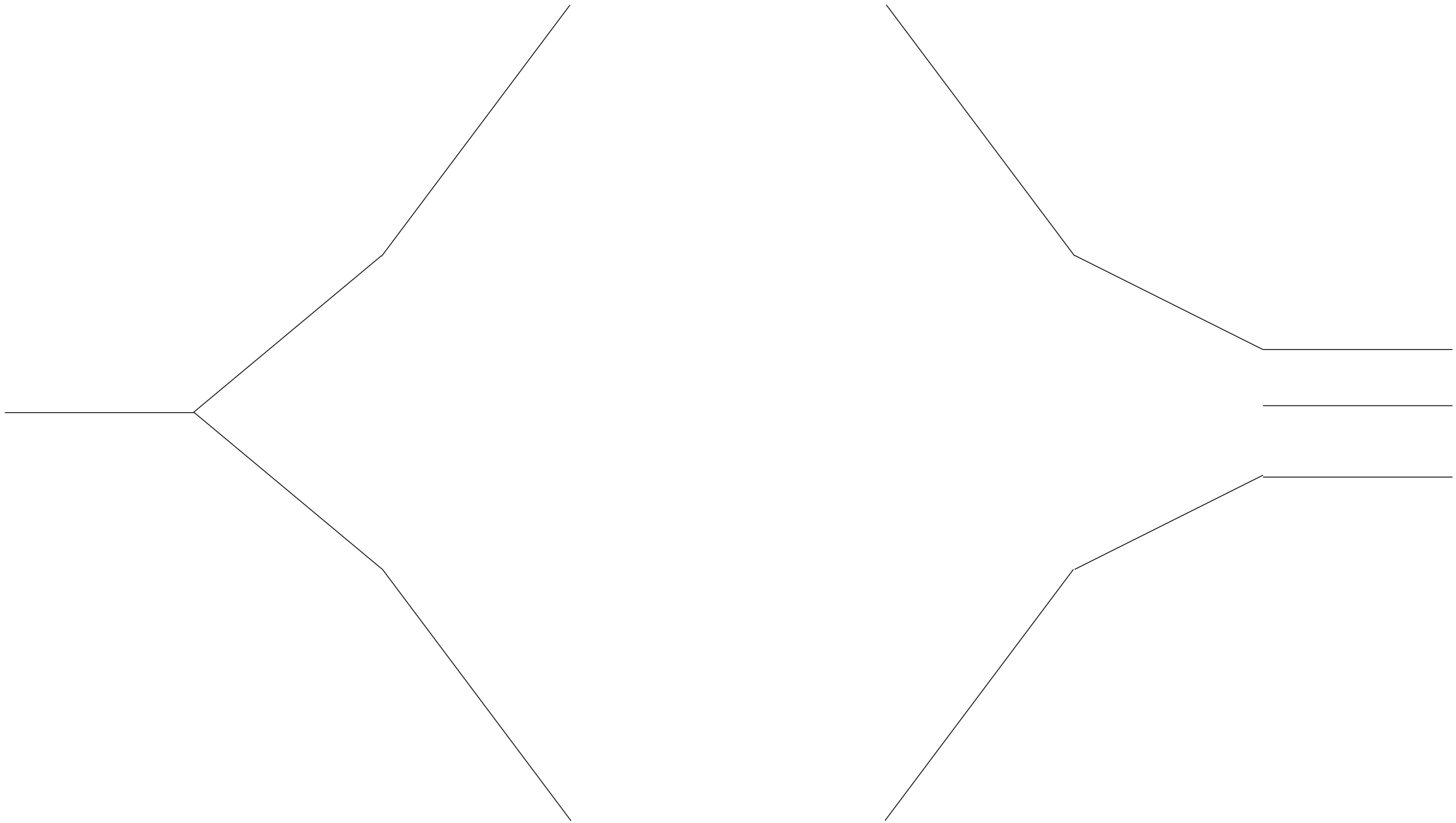
The Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) believes it is important to help stakeholders (e.g., manufacturers, health-care professionals, patients, patient advocates, academia, and other government agencies) navigate the regulatory landscape for medical devices. Towards this goal, on November 21, 2014, CDRH held an open public workshop on its White Oak, MD campus with the aim of fostering an open discussion on the scientific and regulatory considerations associated with the development of Brain-Computer-Interface (BCI) devices, defined for the purposes of this workshop as neuroprostheses that interface with the central or peripheral nervous system to restore lost motor or sensory capabilities. CDRH plans to use this information to develop regulatory recommendations that will promote innovation while maintaining appropriate patient protections. As a first step, the FDA plans on building on advances in regulatory science and the information provided in this workshop to develop preliminary guidance that provides recommendations for premarket submissions for BCI devices. This paper summarizes the presentations and discussions from that workshop.

doi: 10.1088/1741-2560/13/2/023001

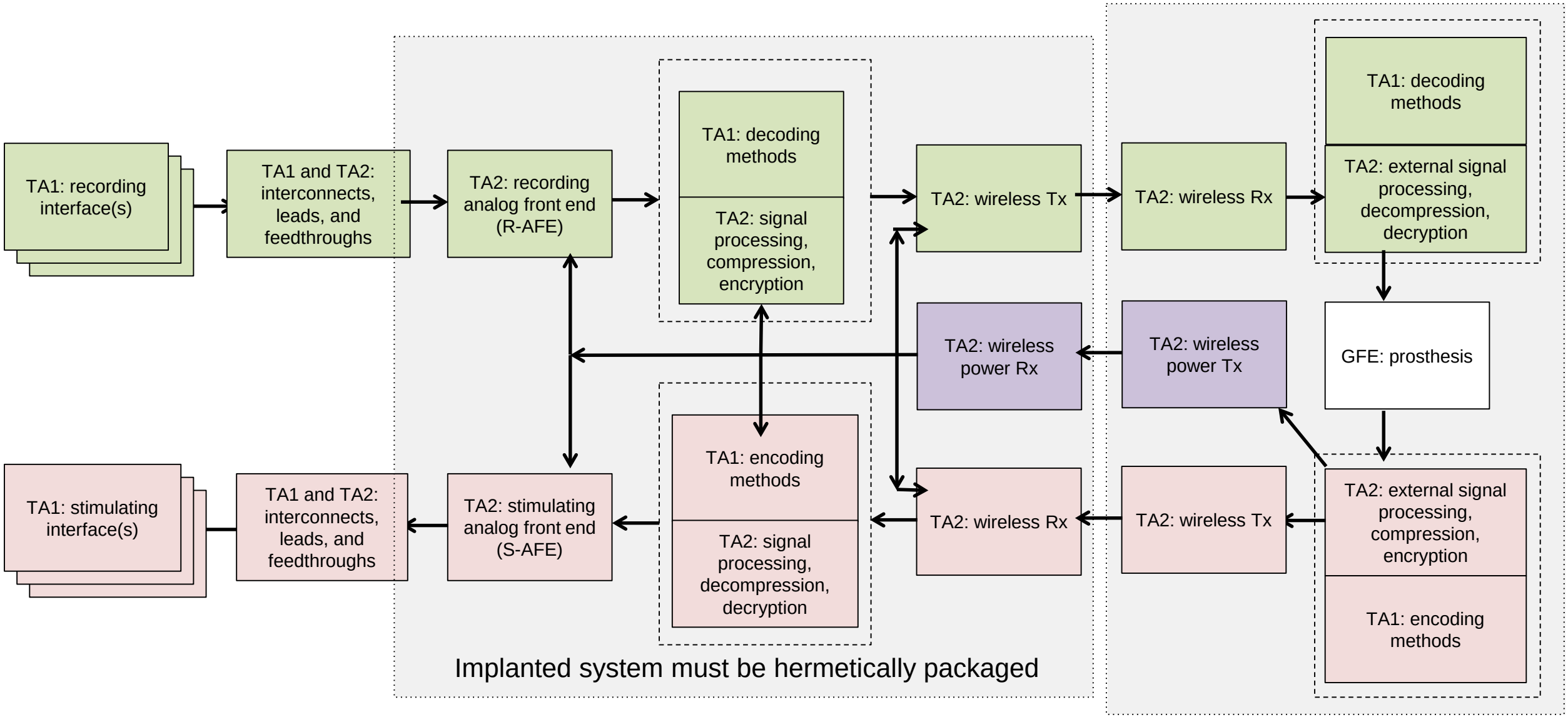
Case study from other disciplines

$$\mathrm{SNR} = \frac{P_{\mathrm{signal}}}{P_{\mathrm{noise}}},$$

Study	Signal	Noise
Kozai/Kipke 2012 carbon fiber	mean unit Vp-p	2*SD of the signal after removal of discriminated spike waveforms
Ludwig/Kipke 2011 PEDOT silicon	mean unit Vp-p	2*SD of the signal
Ludwig/Kipke 2009 silicon	mean unit Vp-p	6*SD of the signal after removal of discriminated spike waveforms
Sanchez/Carney 2006 microwire	mean unit Vp-p	“dynamic range” of nonspiking baseline
Suner/Donoghue 2005 “Utah” array	mean unit Vp-p	2*SD of the residuals when mean waveform is subtracted from all individual waveforms
Nicolelis/Wise 2003 microwire	mean unit Vp-p	lowest Vpp seen within the unthresholded spike discrimination window



HAPTIX


TA1: recording interface(s)
TA1 and TA2: interconnects, leads, and feedthroughs
TA2: recording analog front end (R-AFE)
TA1: decoding methods
TA2: signal processing, compression, encryption
TA2: wireless Tx
TA2: wireless Rx
TA1: decoding methods
TA2: external signal processing, decompression, decryption
TA2: wireless power Rx
TA2: wireless power Tx
GFE: prosthesis
TA1: stimulating interface(s)
TA1 and TA2: interconnects, leads, and feedthroughs
TA2: stimulating analog front end (S-AFE)
TA1: encoding methods
TA2: signal processing, decompression, decryption
TA2: wireless Rx
TA2: wireless Tx
TA2: external signal processing, compression, encryption
TA1: encoding methods
Implanted system must be hermetically packaged

Topics identified by HAPTIX investigators

System-level
VRE/Limb API and connections to wireless/wired connections
Weight, size and power source
Confidentiality, Integrity, and Availability (CIA triad)
Trial management (executive software, data collection)

User-friendliness
Implantable interconnects
Post-haptix implantable hub
User interface (power, charging, calibration)
Limb socket, best practices for attachment and sockets
Mounting for external system
General guidance on alignment of transceivers

Safety and Reliability
Common assumptions
Guidelines on mechanical testing (flex / stress / crush / tethering force)
Electrical safety
Materials, Biocompatibility, and Sterility

Informatics
Validation of HAPTIX Metrics and Milestones
Define "recalibration“, gradations of pressure, other terms
Universal studies (participant survey questions, baseline ARAT)
Data file formats (Metadata minimum requirements)

Important lessons:

Define the scope of the problem

Heterogeneity can have value

Good intentions aren’t enough