EPoSS AMNBS Working Group

Renzo Dal Molin — *Sorin CRM, FR*

Jesús Ruano — IKERLAN, SP

Setting up of MNBS topical group in EPoSS chaired by Jesús Ruano and Renzo Dal Molin

EPoSS
European Technology Platform on Smart Systems Integration

- Federate fragmented
  - Industry
  - R&D
  - Supply chain
- Facilitate communication with
  - National Authorities
  - EC, ETPs, JTIs
  - End users
- Set up collaboration networking
- Position papers, roadmaps
- Standardization

Applied MNBS

> MNBS applications in health & (bio-)medical, environment, food & beverage safety

> Sample preparation & detection in a Lab-on-Chip

> Computer-Brain-Interface & neural systems based on photonic transistors

> Body-worn & implanted Bio-MEMS

Belief	Category	Message
1	***Economical context***	Probable scenario is : no growth in EU, progressive recovery in the US, development of emerging countries
2	***Customer financial context***	Hospitals in EU will be heavily exposed to a financial squeeze (cost of older people, lower budget)
3	***Decision Makers***	Payers will get a stronger power at different level
4	***Financial regulation***	DRG Diagnosis-related group will remain one of the key drivers to force hospital rationalization among hospitals
5	***Impact of regulation for medical device industry***	True innovation and not incremental innovation be rewarded, how to gain market access with a adequate /profitable GTM (Go to market) strategy
6	***Medical industry in Europe***	Industry has to demonstrate how it can contribute to healthcare, to employment and exports
7	***Medical industry in US and in Emerging countries***	The increasing barriers to entry in the US (e.g. FDA regulation) will protect position of market leaders in US while the Emerging countries with lower regulation rules will still be for a while an « Eldorado »

	Recomamndation	WHY ?
1	***Lower COGS Efficient S&M Organization***	Mature products are exposed to price erosion. Only lower COGs allow competing for financial negotiations and tenders while retaining some gross margin. In addition SF needs to be either more effective or more efficient (depending on situations)
2	***New Market Access approaches***	The development of new MA approaches (e.g. patient outcome financing) should probably be developed
3	***Develop an efficient Reimbursement process***	Considering the increasing burden of regulatory in EU, it is imperative to be able to conduct efficiently and effectively with the minimal amount of clinical studies required.
4	***Invest in selected real evidence based innovation (premium)***	Only real breakthrough (technical or clinical) can lead to new higher DRGs or to new tariffs rewarding innovations. They are crucial to avoid overall price erosion but they require imperatively to be supported by evidences (mainly clinical)

Current situation leads to anticipate 4 different model in Hospital healthcare MD expenses

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	DESCRIPTION	COUNTRIES	EXPLANATION
NATIONAL PRICING	– Overall macroeconomic price regulation (top-down approach)	– FR, PT, BE	– Centralized approach
PURCHASE MODEL	– Negotiations or tenders via some buying groups – Eventually patient outcome (not easy)	– DE (hospitals) – US (GPOs)	– DRGs approach
REGIONAL MODEL	– Regional tender – Regional reference pricing	– SP, IT	– Transfer of financial responsibility from Central Governments. to Regions – Previous experience with Pharmaceuticals (e.g. Andalucia with Oncology) and Medical Devices in some regions (e.g. Lazio with Medical devices)
PAYOR MODEL	– National tender – Patient outcome financing	– UK (SHA) – NL, US (SFs, ACOs?) – DE (ambulatory)	– Primarily driven by Finance

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The 4 different model will require different actions

	ACTION	ORGANIZATION	REQUIREMENTS
NATIONAL PRICING	– Price negotiation with local healthcare authorities	– Health Economics	– Clinical and HE studies
PURCHASE MODEL	– Pricing model with or without sales force service	– Key Account Management	– Business Case studies – Adaptation of sales force deployment reflecting the type of deals
REGIONAL MODEL	– Price negotiation with local healthcare authorities	– Regional Health Economics	– Adjustment of HE studies to Regional situation – Adaptation of sales force deployment reflecting the price level
PAYOR MODEL	– Elaborated financial discussion with payers	– Health Economics	– Specific financial simulations

Key drivers analysis : Importance and satisfaction

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Improve Outcomes	• Improve therapy clinical outcomes, mortality, re hospitalizations and address co morbidities. Diagnostics and therapies for proactive management of disease
Augment Implant Efficiency & Success	• Improve time and ease of implant. Enhance procedure cost effectiveness. For instance, connectors, lead implantation accessories
Enhance Patient Therapy Acceptance	• Reduce complications related to or caused by system.
Hospital Efficiency	• Improve workflow and systems for managing devices. Address economics of device management. Automation, connectivity, etc…
Device Prescription	• Enable physicians to appropriately identify and diagnose device indicated patients.

Key drivers analysis : Importance and satisfaction

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Improve Outcomes

- => Multiplex diagnostic, on time, 100% reliability , long term performance (if in vivo implantable diagnostic device)
- => Effective replacement / support of the targeted organ or function => cardiac, muscles, nerves stimulations ; artificial organs, tissue Engineering

Augment Implant Efficiency & Success

- => Smart and miniaturized ancillaries / delivery tools
- => Miniaturization, low energy, on time and remote controlled of the implantable device efficiency

Enhance Patient Therapy Acceptance

- => Increase biocompatibility
- => Device preventive monitoring of the possible advers events.
- => Increase the environment patient compatibility of the device (e.g. MRI, …)
- => Stimulate the pro-active patient behavior

Hospital Efficiency

- => Perform progressively the migration of the local unit care organization to multi-actors and remote/centralized organizations
- => Address the traditional reimbursement issues (one patient, one unit care, one device) toward social & medical global services

Device Prescription

- => Innovative Tools supporting the selection of the most appropriate medical device depending on the patient medical conditions and his societal behavior (aside the disease diagnostic).

PIP breast implants: "learn the lessons of this fraud"
ENVI **Consumers** / **Public health** − 26-04-2012 - 10:45

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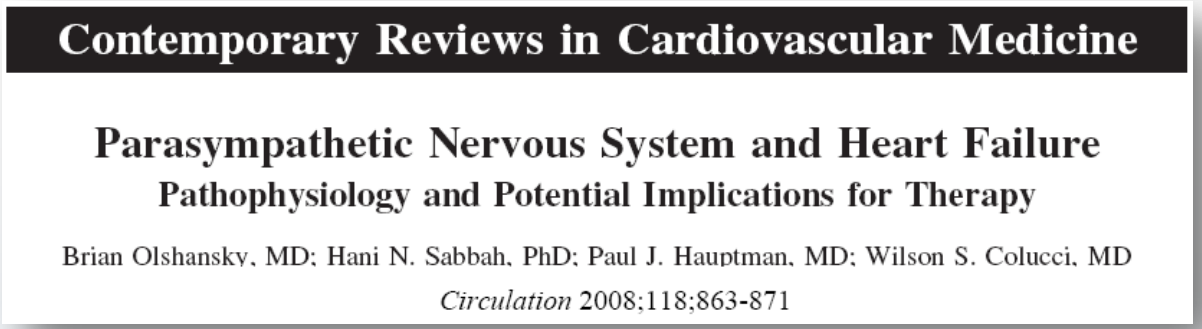
- the strengthening of the designation and control of Notified Bodies in the EU, also with respect to their skills and resources;
- better vigilance reporting and coordination of member states on incident assessments;
- increased and unexpected controls of manufacturers by notified bodies based on experience from the post-market phase;
- establishing tools to ensure the traceability of devices, in particular implants;
- establishing registers for implants and having the registers interconnected.
- the need for innovation in order to address current and future healthcare challenges.
- need a pre-market authorization system
- an appropriate clinical evaluation of clinical data is required for all medical devices before they are marketed. In particular, for both implantable devices and devices in Class III, the clinical evaluation must be based on data obtained from clinical investigations unless it is justified to rely on existing clinical data. Randomized clinical trials needed

Market for microelectronic implants

- The global market for microelectronic implants is expected to experience an 8.9% compound annual growth rate (CAGR) over the forecast period. BCC Research found that the fastest-growing segments of the market are:
  - ear implants with a projected CAGR of 18.2%
  - neurostimulators (10.5%)
  - implantable drug pumps (10.5%)
  - cardiac implants and accessories (7.4% and 8.4%)

Vagal stimulation in HF



Contemporary Reviews in Cardiovascular Medicine

Parasympathetic Nervous System and Heart Failure

Pathophysiology and Potential Implications for Therapy

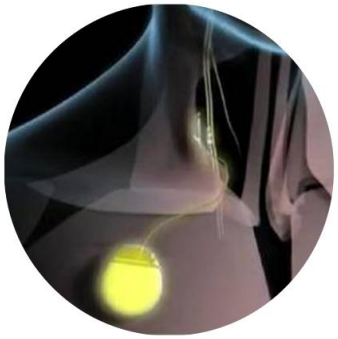
Brian Olshansky, MD; Hani N. Sabbah, PhD; Paul J. Hauptman, MD; Wilson S. Colucci, MD

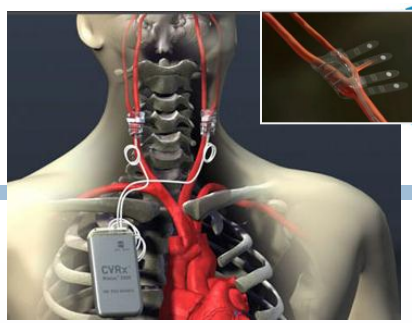
Circulation 2008;118;863-871

- Anti-inflammatory
- Heart rate control
- Increased heart rate variability
- Improved baroreflex sensitivity
- Changes in NO expression
- Changes in cytokine expression
- Antiarrhythmic effects

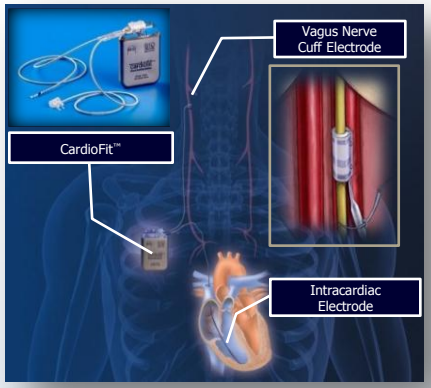
- **Vagal nerve stimulation**
- **Carotid baroreceptors stimulation**
- **Aortic baroreceptor stimulation**
- **Spinal chord stimulation**
- **Renal denervation**

- Biocontrol (Medtronic)
- Boston Scientific



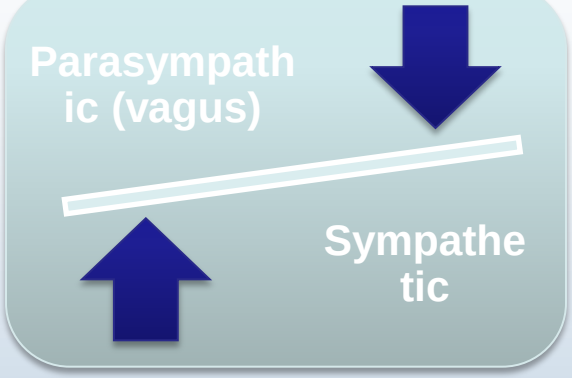


- CVRx

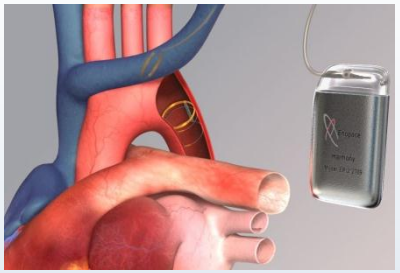


VNS

BAT

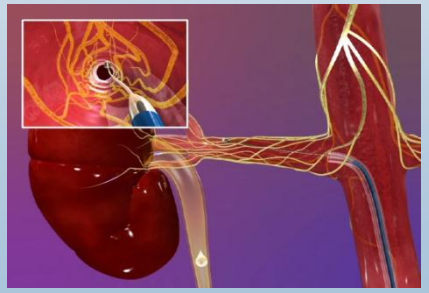


AST



- Enopace

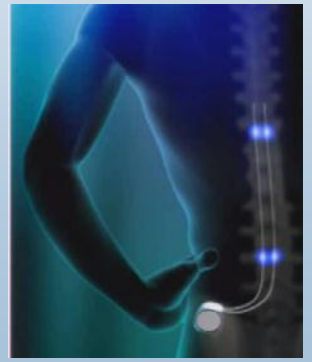
RND



- Medtronic
- *St Jude medical*
- *Biosense Webster..*

SCS

- Medtronic



Emerging field : Traumatic spinal cord individuals (tetraplegics, LIS (locked-in-syndrom))

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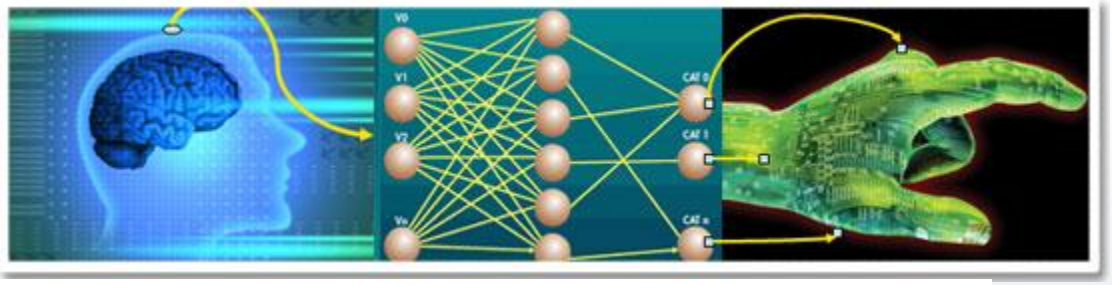
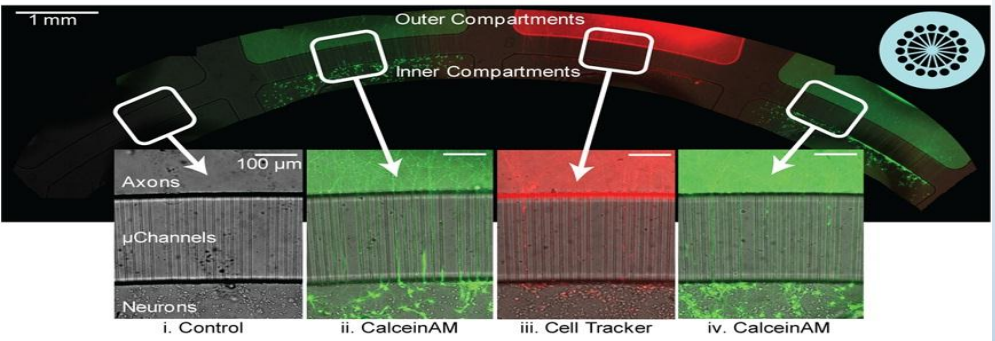
Brain-Computer Interfaces & Neuroprostheses (e.g.: Braingate)



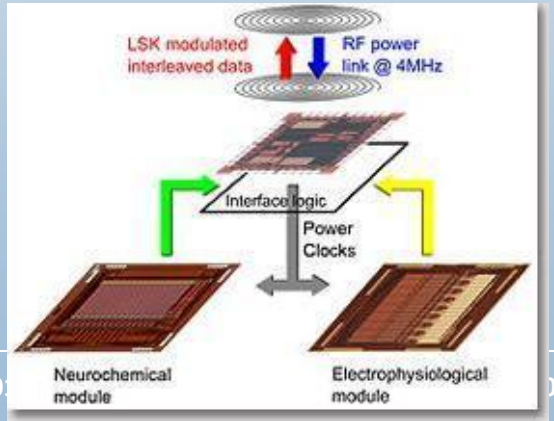
Electro-corticography
Non invasive potentials
Local field Potentials
Single and multi-unit activity Surface EMG



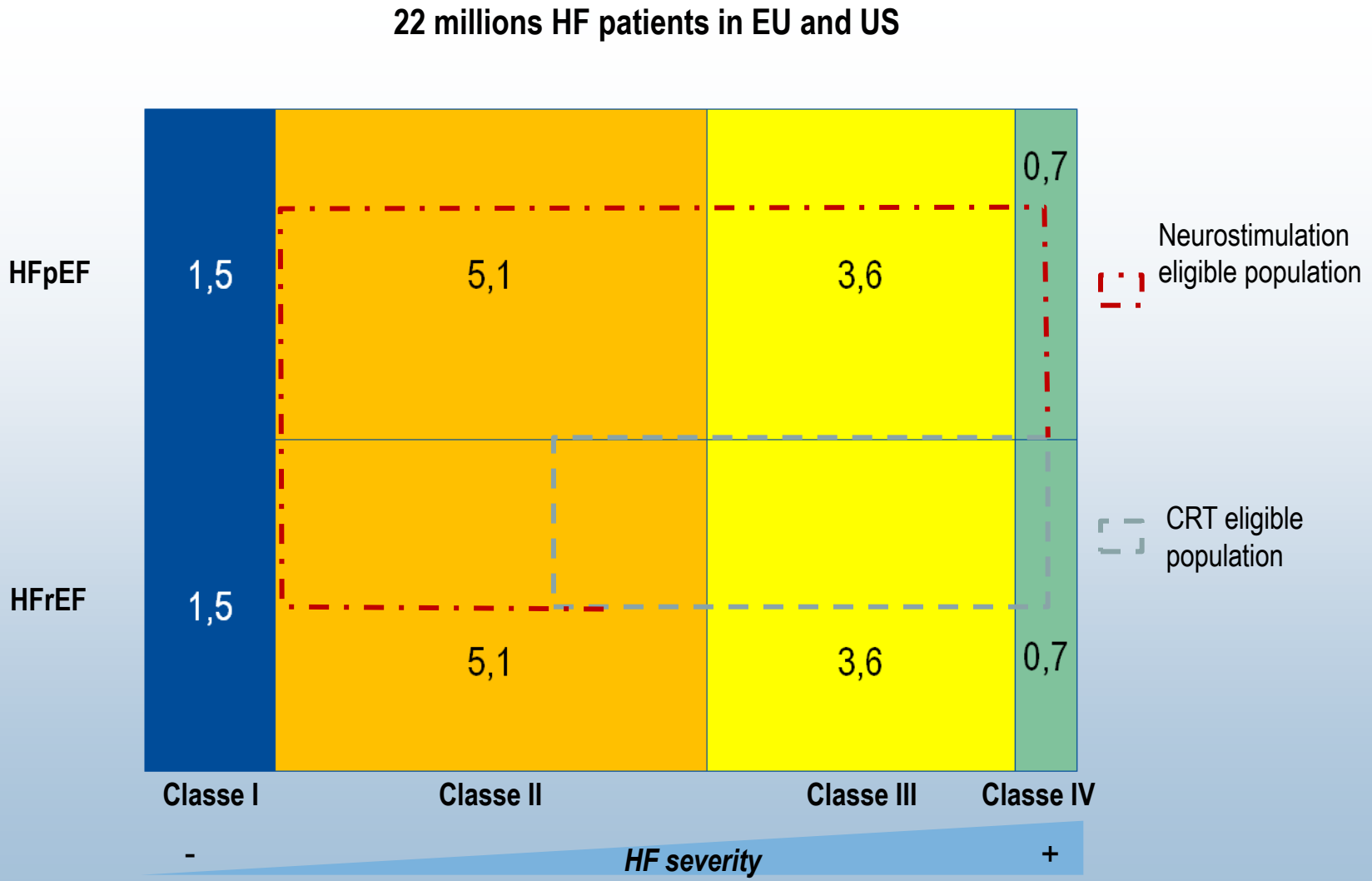
Focus on using micro-fabrication techniques to create novel high-throughput platforms

Simultaneous detection and sensing of Neuro-chemicals and electrophysiological field potentials, using

- multi-channel Potentiostat,
- multi-channel Neuropotential Monitoring
- Head-mounted Imager
- RF Telemetry and
- Power Harvesting



Neurostimulation market in HF is estimated 4 times the CRT market



Mobile Technology and Health Care

- 90% of the US population has mobile phones
  - 64% of physicians use a smartphone today
  - 81% of the physicians will use a smartphone by 2013
  - About 5000 health and medical applications currently available in the market for smartphone user
  - Stanford School of Medicine is giving the iPad to all incoming medical students

- 78% of the US population is interested in mobile health solutions
  - ~15% are extremely interested in mobile solutions
  - 19% of responders would upgrade their current mobile phone plan to access wireless health services
  - 11% would switch carriers to get access
  - ~40% said mobile health would supplement the medical care they received from their doctor
  - 23% believe mobile health services could replace doctor visits

Source: Manhattan Research and mobihealthnews

Mobile Technology becomes Personal Technology - World Wide

- 42% of teens can text blindfolded!
- 173 M smartphones sold in 2008
- 31 M people viewed mobile ads in 2008
- >20% now have only mobile no land line
- **2013 US mobile market > 100% per capita**

Thank You

- renzo.dalmolin@sorin.com
- http://www.smart-systems-integration.org