Translational Challenges for BCI: Learning from History

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Translational Challenges

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November 21, 2014

Today We'll Focus On…

- What the NeuroControl Freehand experience taught us about the realities of small markets and patient-focused applications.
- What FDA's Innovation Pathway 1.0 taught us about the regulatory challenges of BCI.

Regulatory Challenges

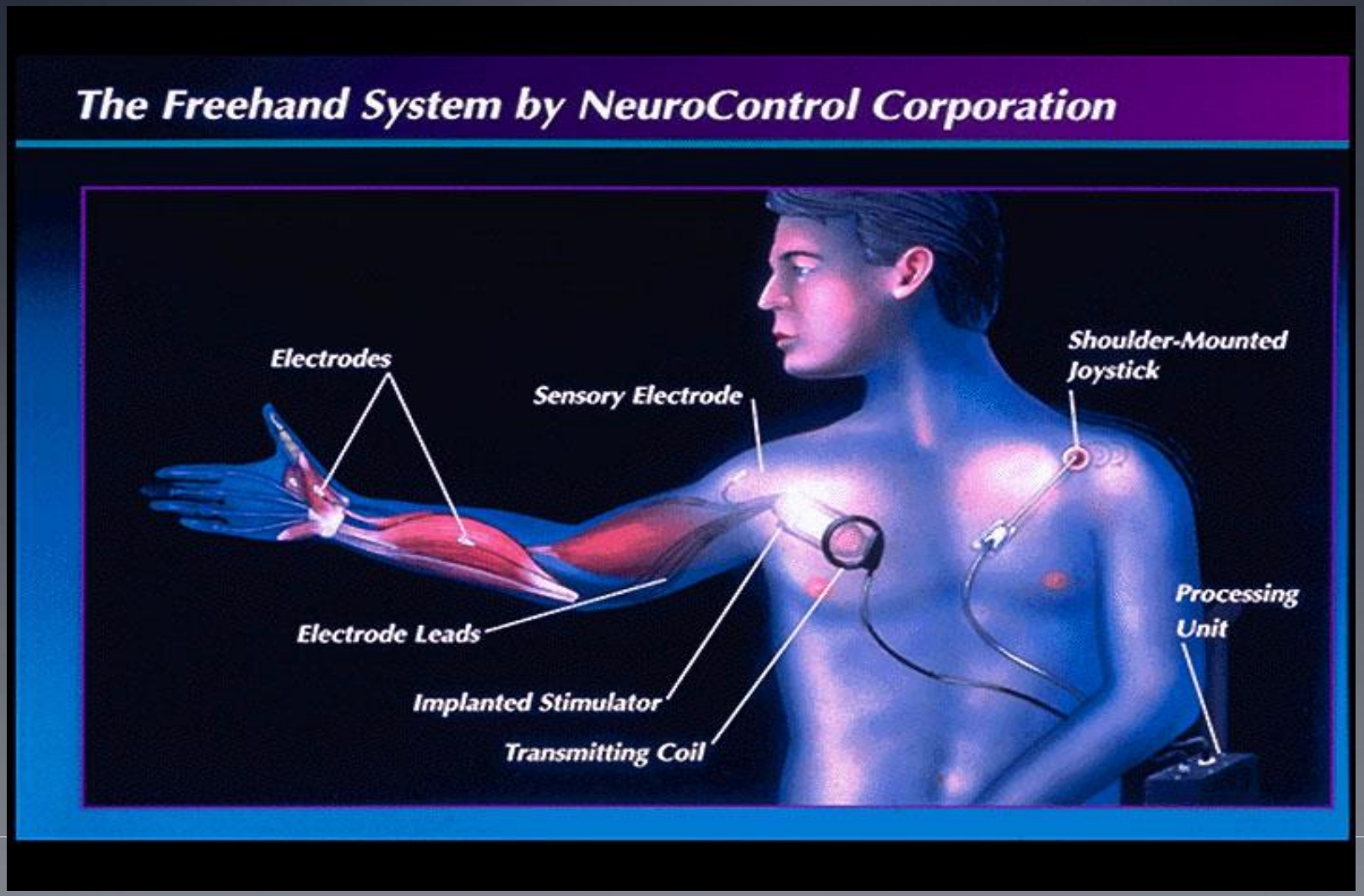
- Not just the challenges faced by researchers and industry in meeting the regulatory requirements
  - E.g., what bench, animal, and clinical tests are required….

BUT ALSO

- The challenges faced by FDA as paradigm-shifting applications are submitted.
  - What policies and practices might need to be reworked for the BCI community?
  - How can one single application be used as a generic test case?

Freehand Lessons Learned: Challenge of Small Markets

The FREEHAND System



History

- An entity beyond the conventional academia is required to achieve clinical deployment and adoption
- NeuroControl Corporation
  - Founded ~ 1993
  - Based upon research at CWRU
  - Venture funded
  - Achieved a PMA (Freehand ®) and HDE (Vocare ®)
  - 250+ FHS and 50+ VBS implants; Followup studies show that patients continue to use daily; Seek support
  - NCC removed SCI products off the market in ~1998

What happened to the FREEHAND System?

- If it worked so well, why is it no longer on the marketplace?
- As a permanent implant, it is still being used by majority of approximately 250 implanted patients worldwide.
  - Patients overwhelmingly adopted it for daily function.
- Patients and docs still ask for it.
- No company exists to support their on-going use.
  - CWRU FES Center supports users as much as possible.

"I will note the 9th of September 2006 as the date when I got a spinal cord injury for a second time!"

-- Freehand user, after system needed replacing

Freehand implant was replaced over the summer of 2007.

FREEHAND System Target Marketplace

The technology is extremely efficacious, safe, and beneficial to patients. The patient stories have great media appeal.

BUT…

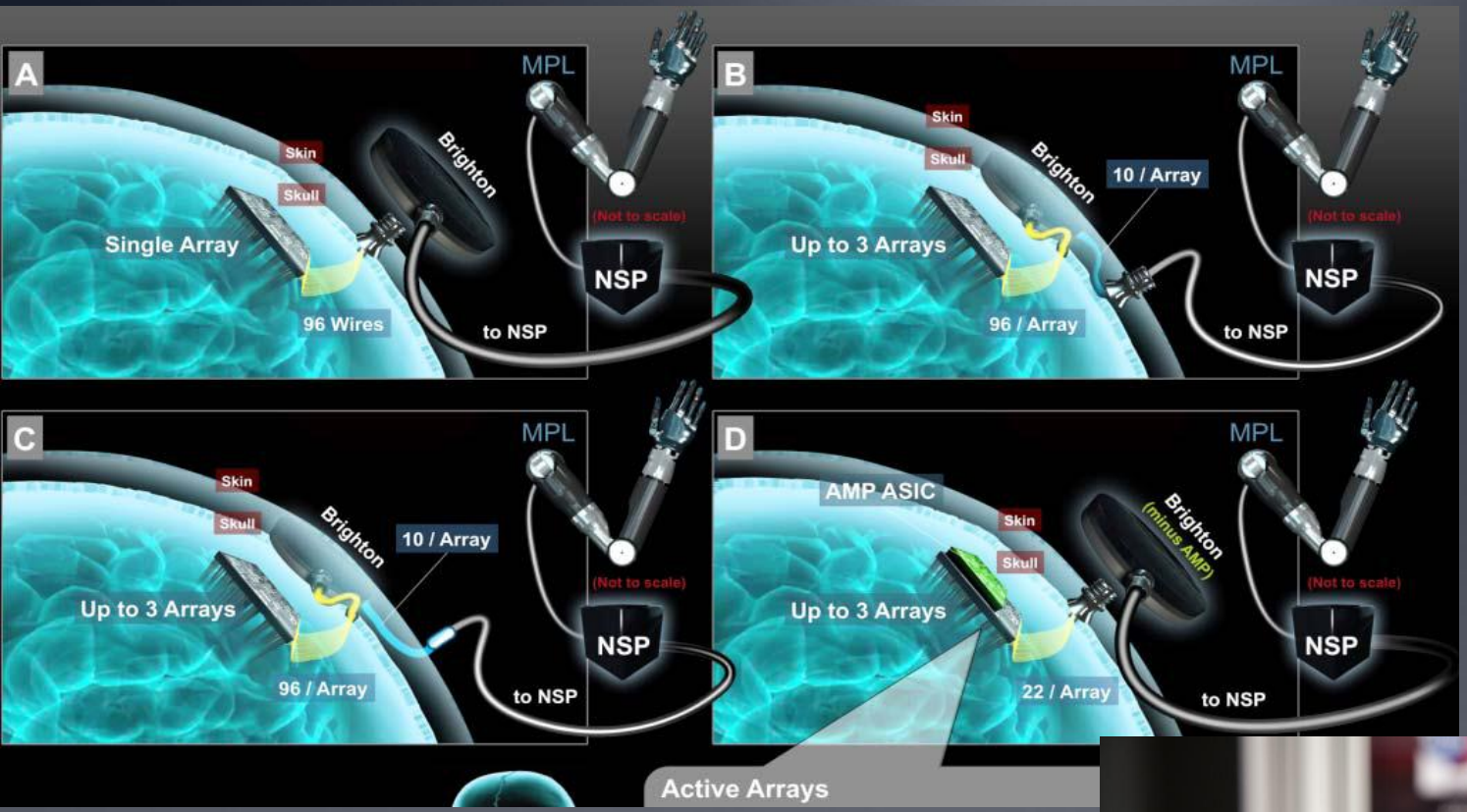
- SCI is very small market (Real US Prevalent Base = <10,000), and demographics are stagnant if not shrinking
- Patients are economically disenfranchised
- Reimbursement Coding not established / rules are changing
- Market place unsubstantiated
- Relatively non existent multidisciplinary clinical care teams required
- Point of sale process is complex
- Manpower intensive presurgical assessments, intra-operative procedures, and postoperative support
- Expensive to commercially manufacture and support

Summary

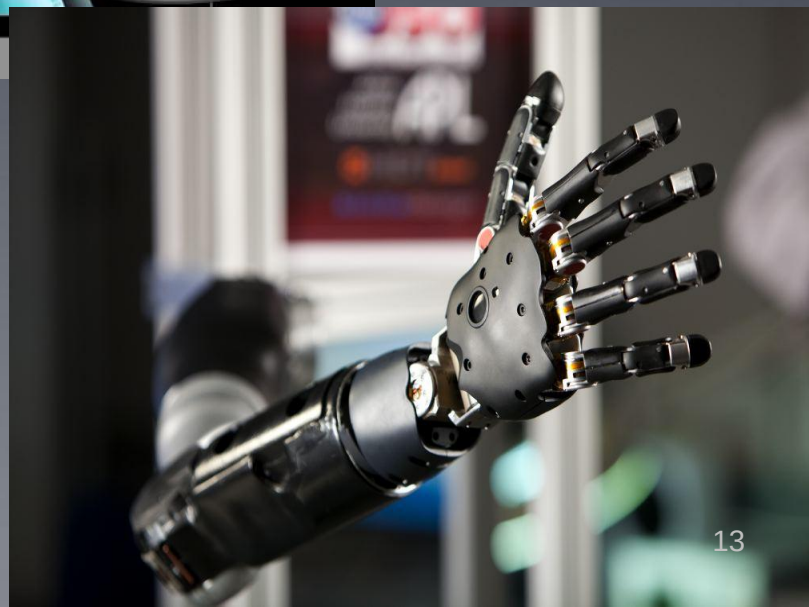
- Freehand System - Clinical success for orphan market
- NeuroControl - Business failure for orphan market
- For BCI, same concerns will exist.
  - Regulatory requirements need to be balanced against the extremely limited options for these patients.
  - Viability of the business model is key.

Lessons Learned from Innovation Pathway 1.0

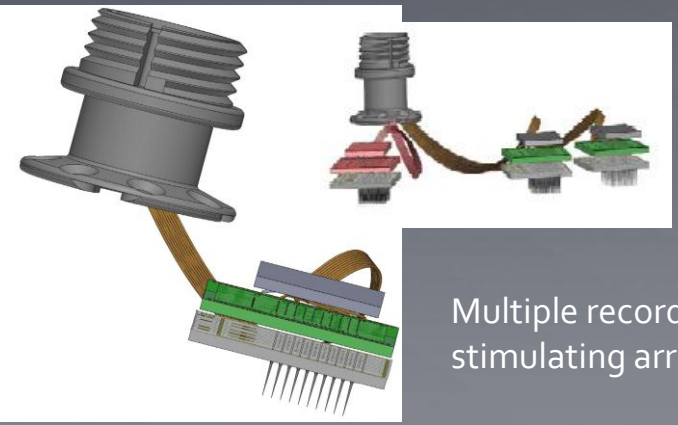
Distinct Devices Comprise the System



2. Prosthetic / Robotic Arm



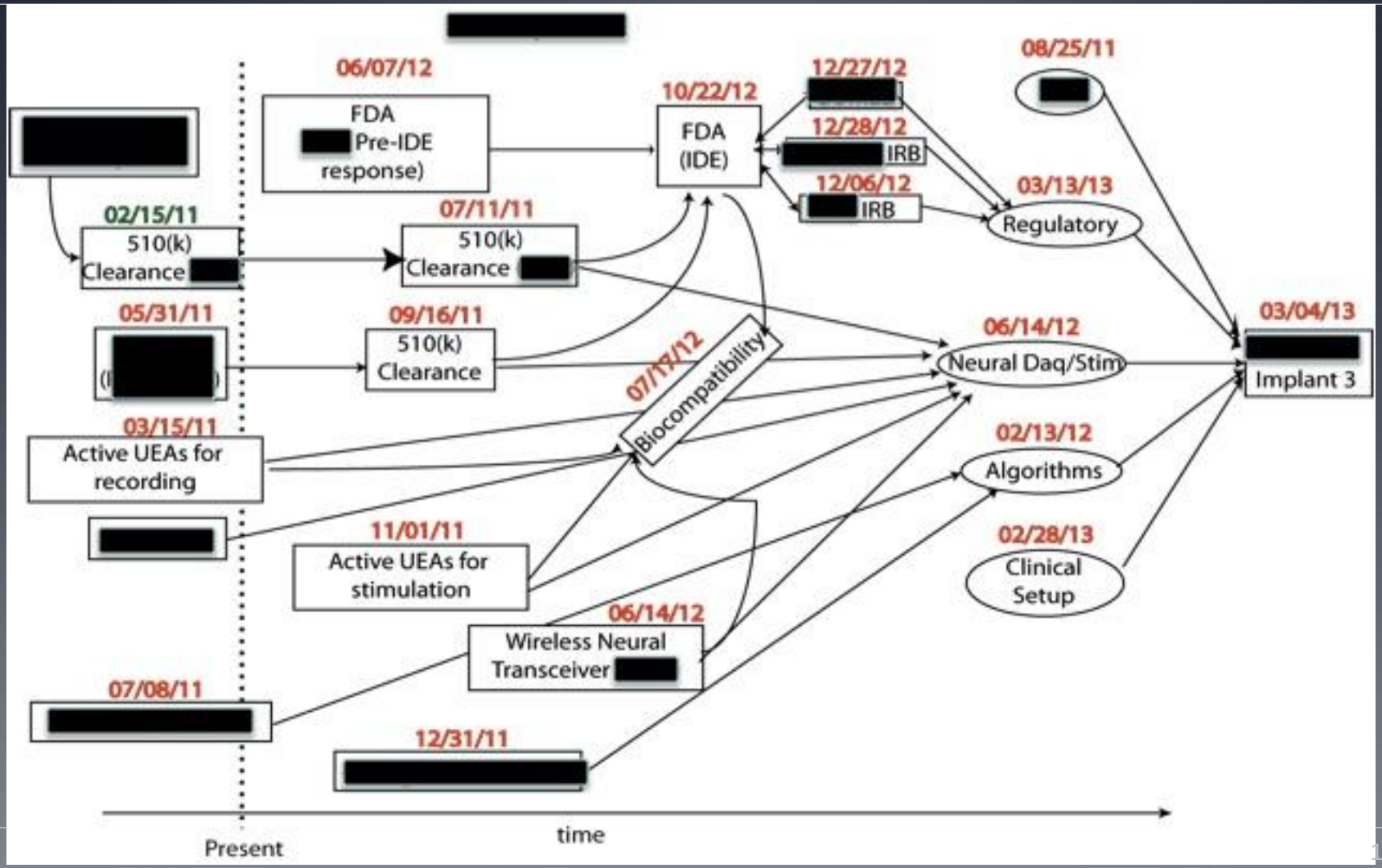
1. Cortical Controller w/ Arrays



Multiple recording and stimulating arrays

Multiple Regulatory Submissions Require Coordination

Example: Planned submissions leading up to the third human implant



Regulatory Challenge

- BCI will involve the translation of components that
  - Meet the definition of a medical device by themselves;
  - But have limited utility unless used as part of a system.

Is it possible to create a pathway that allows components to be marketed "generically" in order to allow future research and efforts, and the development of commercial systems for clinical use?

Questions for Discussion

C. Device Modularity (p 9-10)

- What are the important technology elements to standardize for BCI technologies? Apart from standardization, what are other potential solutions to addressing modularity concerns?
- 2. What are the major translation challenges for BCI technologies and how can they be practically addressed?
- 3. Timing of standardization relative to technology development is important in terms of enabling and speeding innovation and standardization is a key element in assuring safe and effective adoption of modular BCI devices. **Is the time right for standardization of inter-connections of modular BCI devices or is it still premature to do so?**

Questions for FDA

- How might FDA permit market approval / clearance for just one component of the system?
  - What will the indications statement look like for each component of the system?
  - In the absence of standards, what risk-based approach can be used to define “compatible”/”interoperable”?