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Concept, Challenges, Uptake and Adoption of Atrial Fibrillation Ablation: A Pharma Industry View

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Pan-Stakeholder Registry: Atrial Ablation

Challenges from a Pharma Point of View

- Atrial Fibrillation remains a multi-modality treatment
- Even the devices that hope to eradicate atrial fibrillation may require drug therapies
- FDA “Indications” at times risk being reduced to an artificially narrow clinical situation better suited for proof of concept than the complexities of long term patient care
- When pharmaceuticals and devices are needed together the separate laws and reporting regulations don’t always work well together
- When a drug is needed as an adjunct to a device where do you find the drug labeling?
- When drug safety problems emerge in a device trial is there always adult supervision of the drug problem?

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What works well today

- **Pharmaceutical therapies to treat device complications**
- **Devices when drugs aren't needed or are only needed in very limited ways**
- **Coating a device with a little drug**
- **Interventional cardiology research**
  - **More likely to be:**
    - **Adequately sized**
    - **Randomized and blinded**
    - **Clinically important end-points**
    - **Reproducible in multiple centers**

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What doesn't works as well today

- Pharmaceutical therapies that need complex protocols
- Getting a decent drug history out of a registry
- Adjuntive therapies that have their own serious side effects (and don't count on pharmacogenomics to make warfarin safe beyond the starting dose)
- How do we develop adjunctive support with out running afoul of 'off-label' promotion and its multi-billion dollar fines.
- Where again do I find the Device Label that spells out all of this … or was this just a tool 510(k) approval…

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What is the Highest Short Term Priority

- **Pharmaceutical Therapies**
  - **Partnerships, partnerships, partnerships**
  - **There are some settings where adjunctive use would make a good new claim and belong in drug labeling with descriptions of clinical trials, adverse events and be worth bringing "on label."**
  - **Clear strategy to:**
    - **Collect drug information**
    - **Monitor and report safety**
    - **Modify labeling, at least for new safety findings**
  - **CDER and CDRH working together at a higher level than just having a primary review center designated**

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What is the Highest Long Term Priority

- **Treatment that works**
  - **If devices can reduce the need for pharmaceutical treatment … that's worth doing**
  - **Realistically some patients will need both … so …**
    - **We need clinical development programs that can identify the contribution of both the drug and the device (without artificially insisting on full factorial designs to identify the exact contribution of each component.)**
- **Ways to do registries that don't look (and cost) like clinical trials**
  - **CDRH is better at this than CDER since they have had to live with uncontrolled unblinded evidence for many devices**
  - **Marry pharmacoepdimiology with devices to create medtech-epidmiology where real world use and rare events can be studied.**
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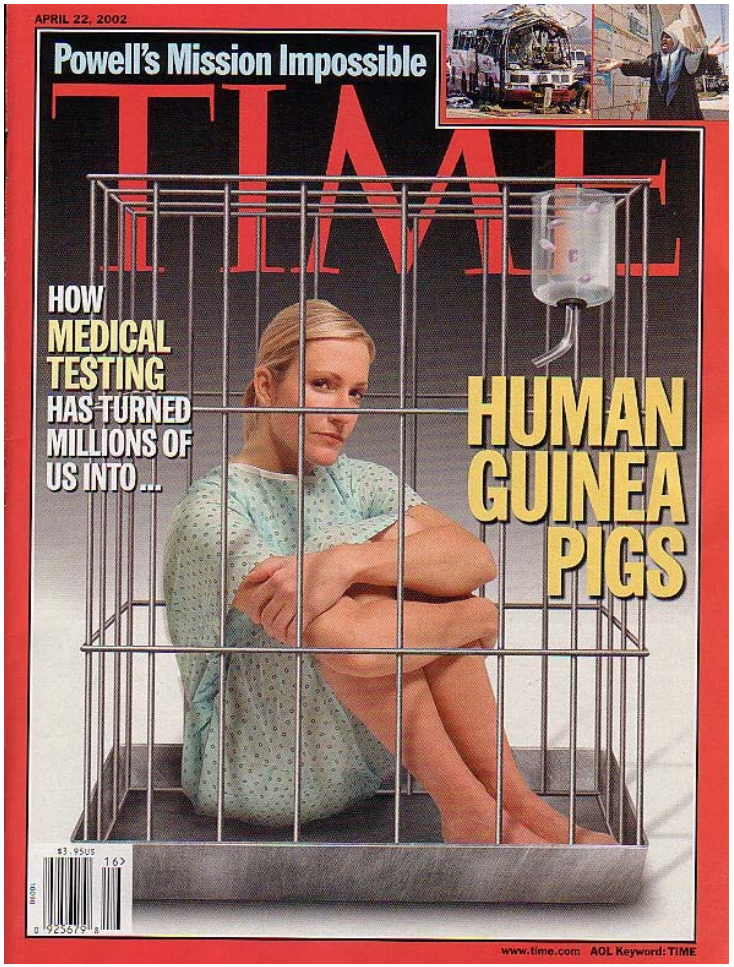
Innovation and Trust



Including trust in FDA, PHARMA, and Medtech

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