



Getting to the Heart of the Matter: Partnerships for Understanding Cardiotoxicity

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FDA



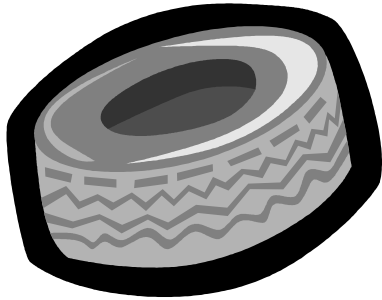
FDA's Mission Statement

“The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation’s food supply, cosmetics, and products that emit radiation.

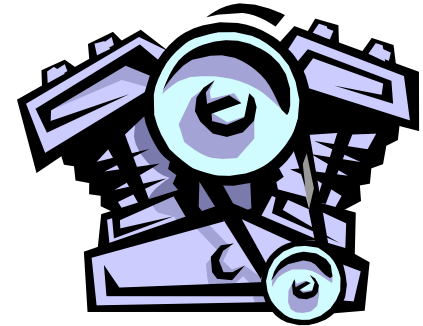
The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.”



Projects



Partners



Partnership



Agreements



Public Health Need



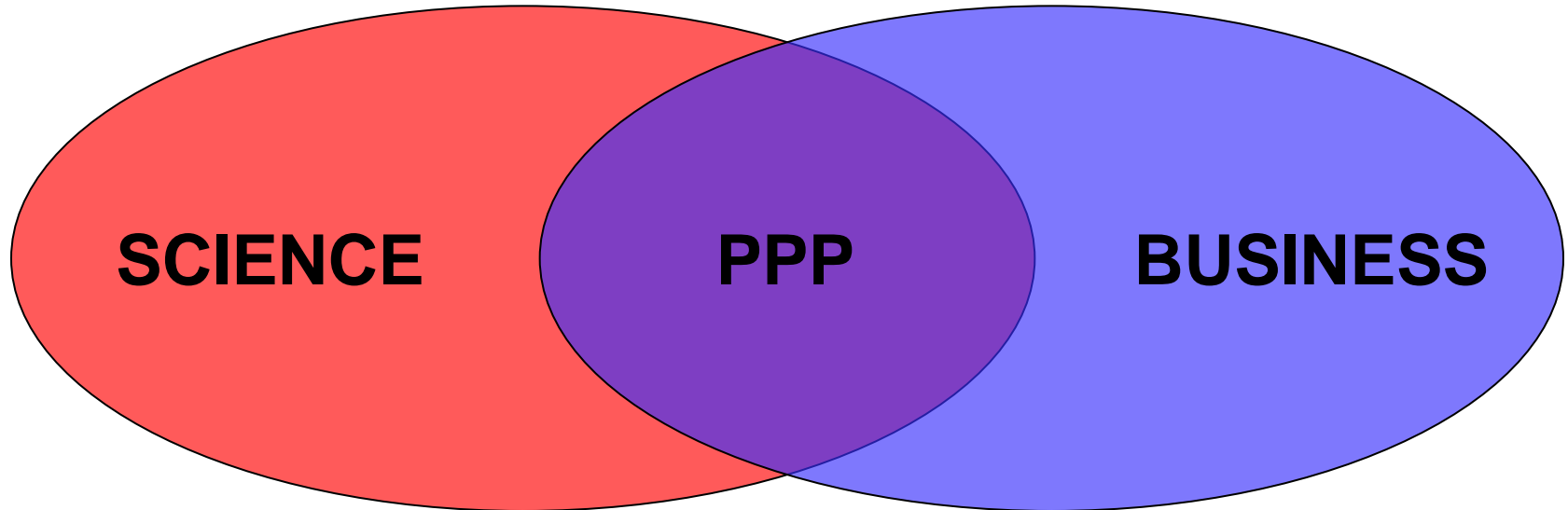
Why Public-Private Partnerships?

- Any single party: limited resources (staff, funds, infrastructure, equipment...), time and expertise
 - Leverage resources and expertise among stakeholders to minimize costs (time and money)
 - Align missions toward mutually beneficial goals
 - Open new lines of communication among partners
 - Create value added for all stakeholders: optimizing economies of scale...advancing public health
- Whole = Greater than sum of individual parts/partners
- Implement economic law of comparative advantages

PPP Operating Principles

- **Transparency: maintain public trust**
- **Inclusion of stakeholders**
 - **FDA, Industry, Academia, Professional Societies, patient advocates, other gov't, ...**
- **Leveraging existing resources**
 - **Existing and prospective data: Data-sharing processes**
 - **Claims data**
- **Focused on Public Health and Efficient Product Development**

Elements of a PPP



- Develop protocols, timelines
- Implement projects
- Determine public health questions
- Obtain stakeholder input
- Identify other efforts: join, expand
- Publish scientific articles
- Interpret scientific data
- Share resources: IP, data, time, etc.

- Develop business plan/strategy
- Create governance/Adm Oversight
- Identify & recruit partners
- Negotiate agreements, IP etc
- Administer/manage contracts
- Manage conflicts of interest
- Develop data sharing guidelines
- Develop reports/output analysis
- Secure funding

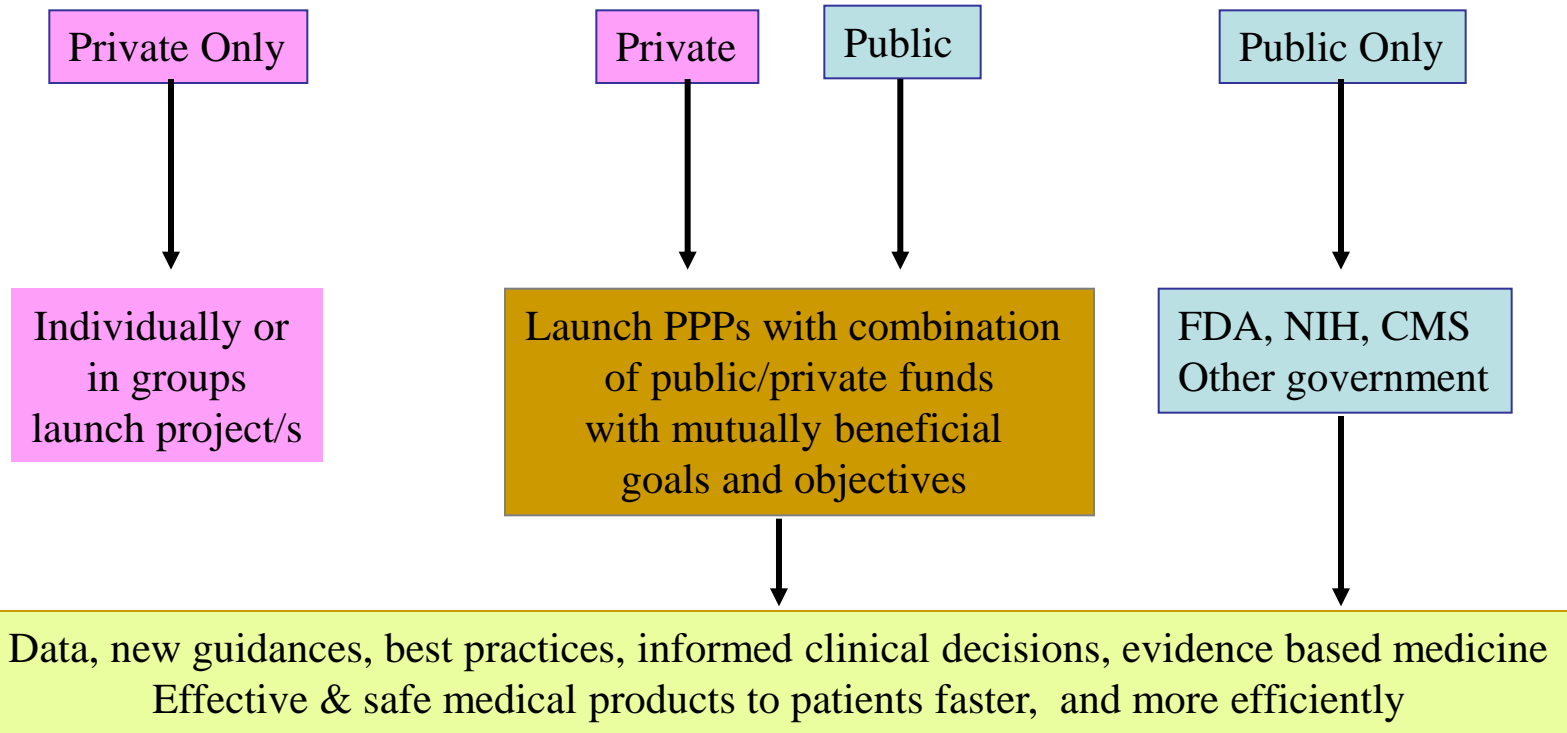
Some Elements of Business Model

- **Pooling: IP, resources, expertise...**
- **Share Data: Proprietary, Pre-clinical, clinical, pro-competitive?**
- **Models: Sematech, SNP & Biomarker Consortia, C-Path Institute**
- **Contracts/Agreements with timelines, deliverables, specific terms and conditions?** (Licenses: non-exclusive commercial, research-use?)
- **Implement *POC* project/s**
- **Develop: Research/predictive tools, know-how, guidances**
- **Employ multiple mechanisms**

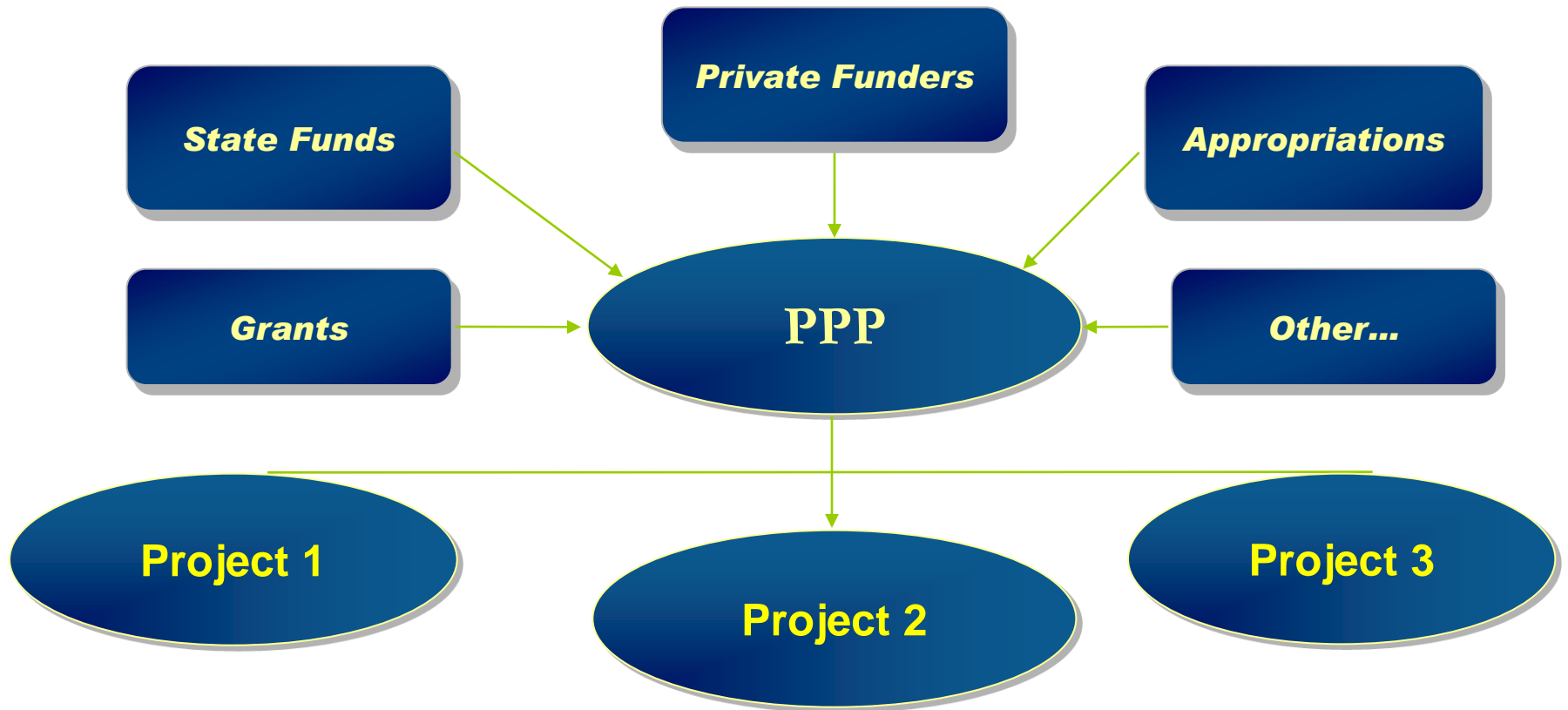
Data/Deliverables ↔ **FDA Guidances** ↔ **R&D, CMS, Clinical Decisions**

General Funding Model

Whole is greater than sum of parts/partners



Potential Sources of Funding



Basic Steps in Collaborating with FDA

(not comprehensive! not consecutive!)

Start with the Public Health Need, **SCIENCE!**
Identify Priorities for multiple stakeholders

Identify gaps/opportunities
(avoid duplication)

- Identify partners: define roles/responsibilities
- Co-develop: proposals, budgets, timelines etc.
- Leverage resources/expertise
- Implement joint *Proof of Concept* projects
- Share data in public domain as quickly as appropriate: Pre & Pro-competitive tools

Some Benefits

PRIVATE PARTNERS: Regulatory knowledge, Predictive Tools & Input in Project Selection

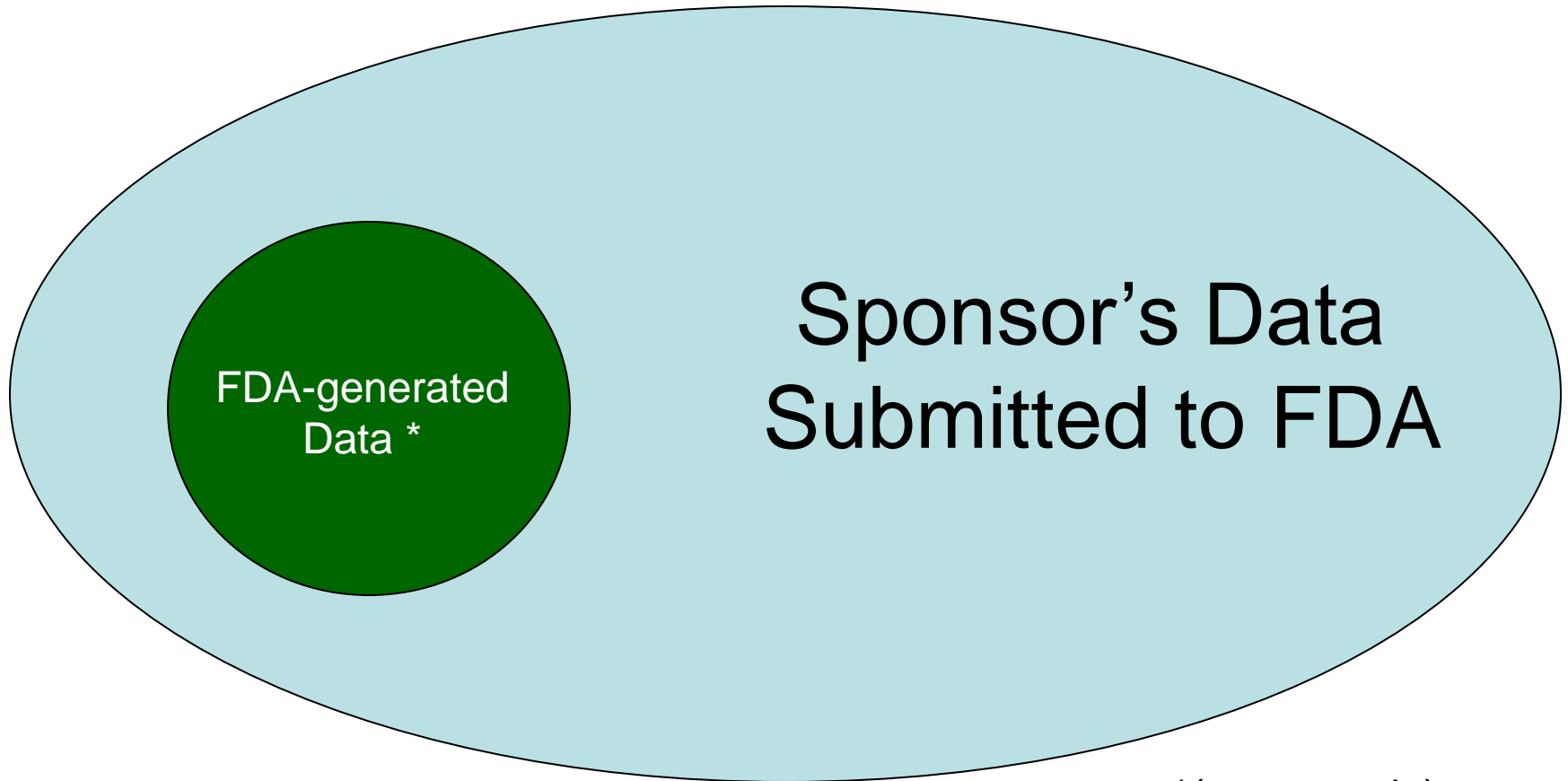
FDA: Guidances, Standard-setting, Evaluative Tools

PAITENTS: Faster, Safer and Cheaper Medical Products!!!!

Data sharing

- FDA has the largest repository of clinical trial data in the world
 - These data are a potential gold mine for new analyses to inform future development of medical products
- , but...
- These data are not owned by FDA
 - FDA is prohibited from disclosing Confidential Commercial Information

“FDA Data”

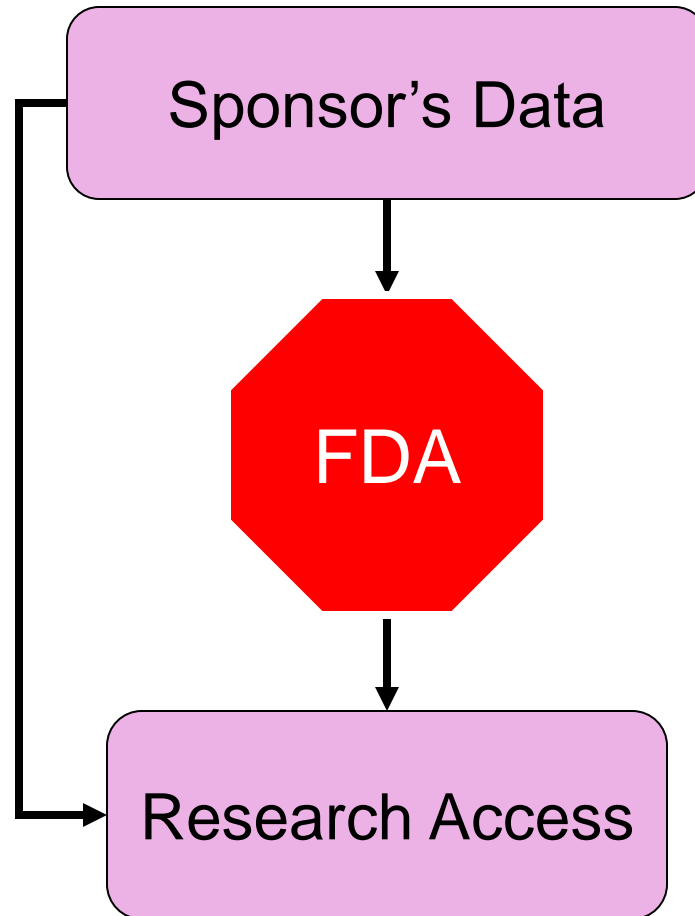


*(not to scale)

Mechanisms for sharing “FDA Data”

- Waiver from data owner
- Contractual or collaborative relationship (abides by same disclosure rules)
 - CRADA, CRA, SGE, Contract, etc.
- Publication of work performed at FDA
- Freedom of Information Act Request

The Other Way



Not a Panacea

- Data standardization is vital to subsequent pooling and analysis
- Existing studies may not have captured appropriate data to evaluate new questions
- There are no perfect clinical trials



Partnership Principles in Action

CSRC and the ECG Warehouse

Before...



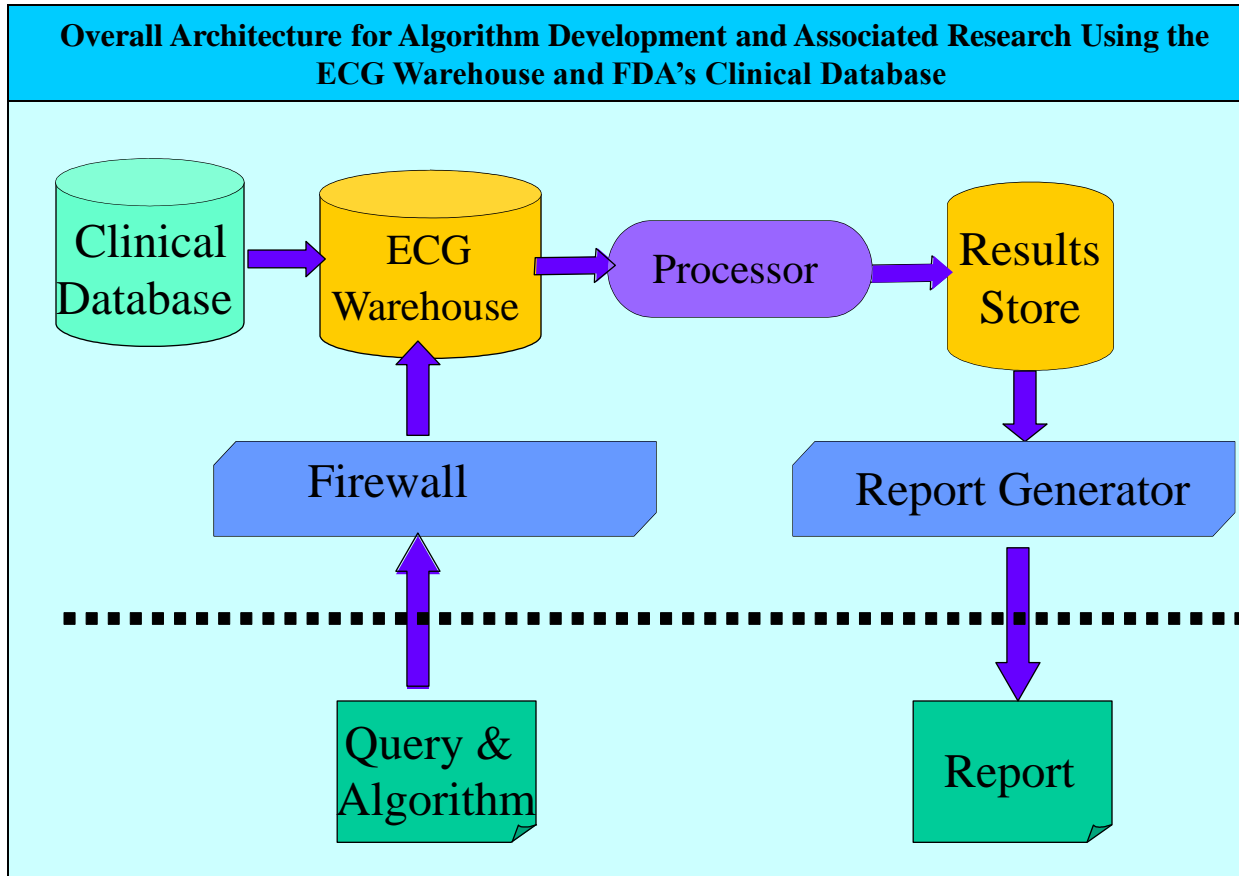
ECG Warehouse:

A Catalyst for the Cardiac Safety Research Consortium (CSRC)

Centralized repository for ECGs

- As flexible as data standard
- Archive in perpetuity
- Reviewer interface through browser
- Systematic collection and review of ECG waveforms as an adjunct to assessment of ECG intervals and overall interpretations

ECG Warehouse



- Powerful tool for reviewers
- Source of critical info. to inform future drug development

Collaboration Model: Cardiac Safety Research Consortium

