CSRC: Who We Are And What We Do

John Finkle MD

Mission

To advance scientific knowledge on cardiac safety for new and existing medical products by building a collaborative environment based up the principles of FDA's Critical Path Initiative as well as other public health priorities

Who We Are

2005: 5 people sitting in an office at FDA

2006: MOU establishing PPP (committees, membership charter)

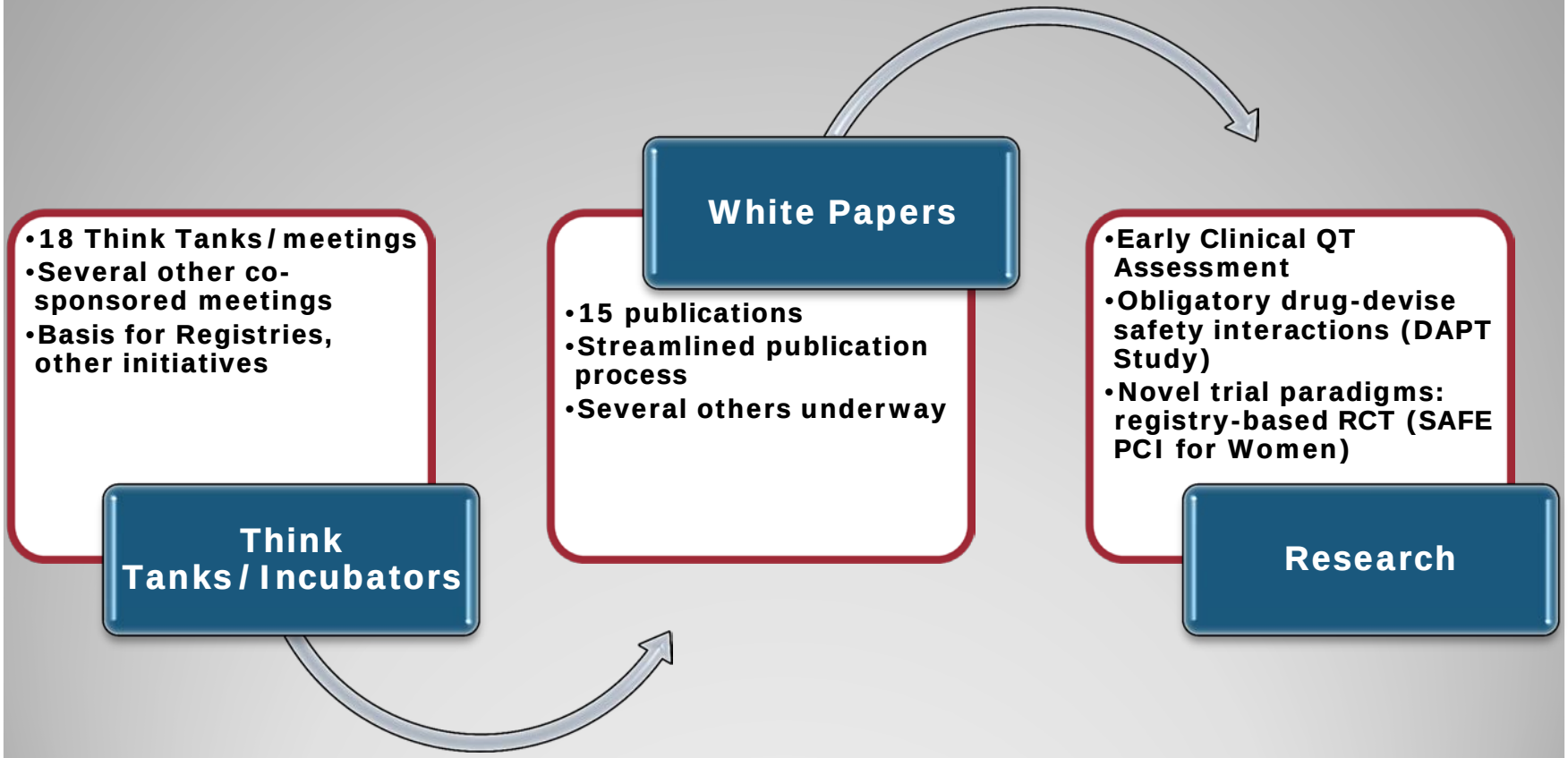
2013:

42 Member Companies	10 Academic Institutions	FDA, Health Canada, PMDA, EU Regulators	Collaborations with ICOS, HESI, DIA, ACC, AHA, American Heart Journal, Center for Business Intelligence
578 Industry Participants	53 Society Participants	220 Regulatory Agency Participants	290 Academic Participants

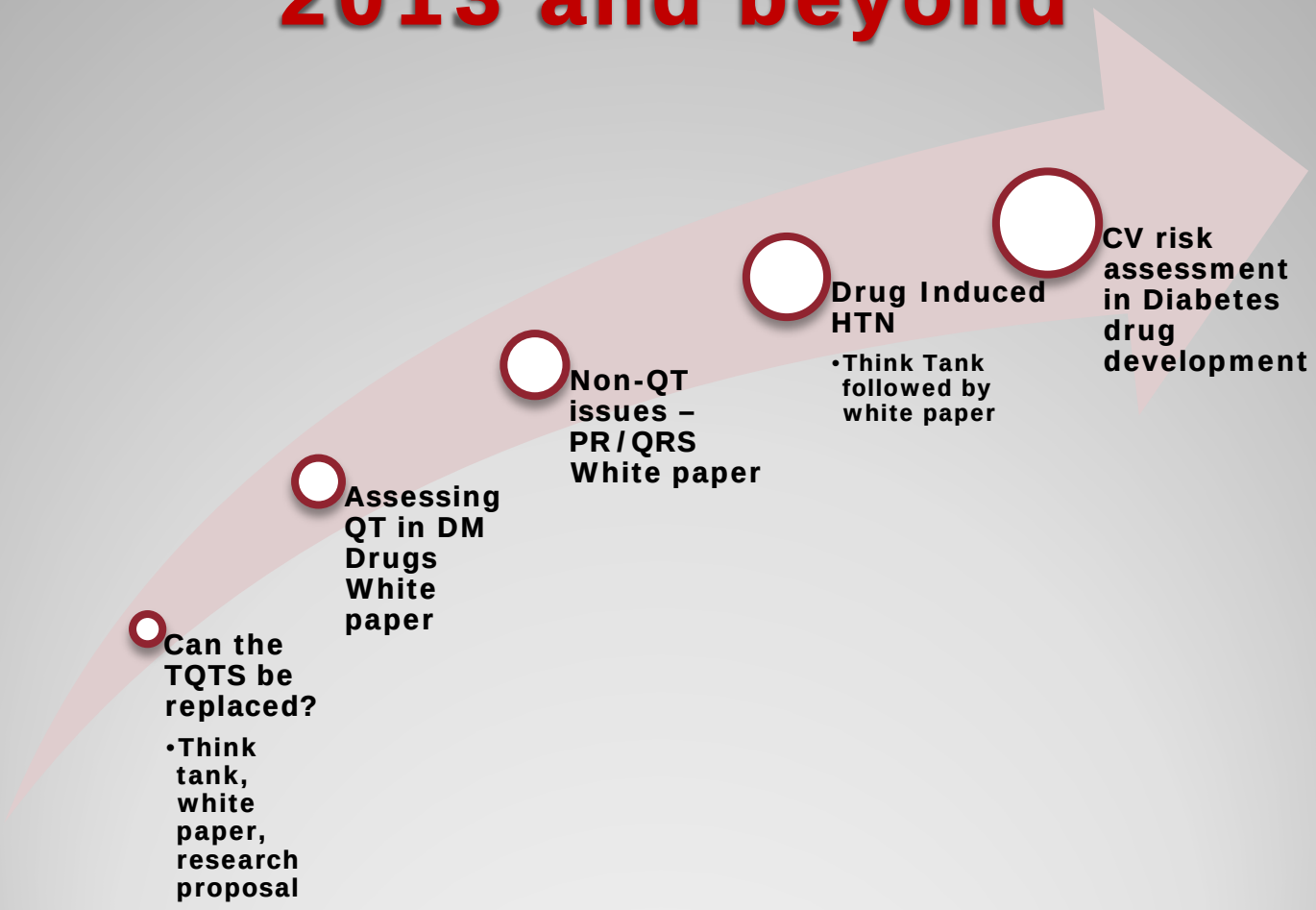
What We Do

- Bring people and groups together to address cardiac safety issues for drugs and devices in all therapeutic areas
- Pre-competitive environment – designed so that participation will benefit everyone – goal of improving public safety
- Pooling of resources allows us to address issues that we all face but may not be able to solve on an individual basis

How We Do It


•18 Think Tanks / meetings
•Several other co-sponsored meetings
•Basis for Registries, other initiatives
Think Tanks / Incubators
White Papers
•15 publications
•Streamlined publication process
•Several others underway
•Early Clinical QT Assessment
•Obligatory drug-devise safety interactions (DAPT Study)
•Novel trial paradigms: registry-based RCT (SAFE PCI for Women)
Research

Major Areas of Focus: 2013 and beyond



Major Areas of Focus: 2013 and beyond

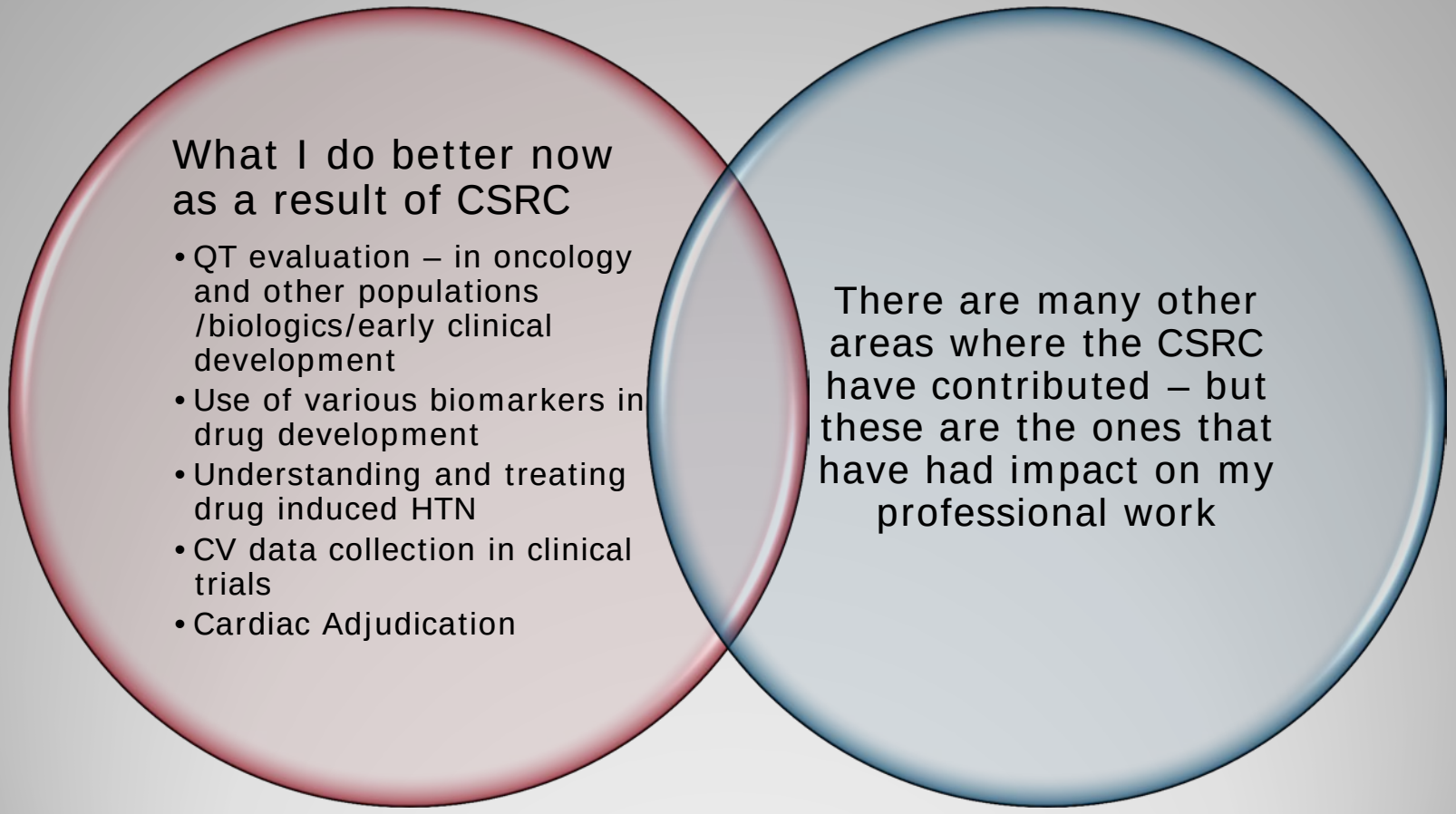
- Use of CV targeted follow up forms for enhanced data collection in clinical trials
- Cardiac Adjudication in clinical trials
- Cardioncology – prevention and treatment of iatrogenic complications of cancer therapy
- Registry based IDE/IND studies (SAFE PCI for STEMI

What Is Success?

Everything we do is focused on:

- Common issues we all face but perhaps cannot address on our own
- Practical advice, suggestions, approaches that we can apply in our day to day work as drug/device developers or clinicians
- Improving efficiency, effectiveness, overall safety of drugs/devices that ultimately make it to patient use

CSRC Benefits



Summary

There are areas that everyone can find direct benefit/take home for their “day jobs”

Success is dependent upon your participation

- **Participation on a project team**
- **Leading a project**
- **We need your proposals!**

CSRC will provide infrastructure to ensure your project/area of interest successful in a reasonable time frame