



CSRC: What is CSRC, How Does It Work and Why We Have Joined Together?

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Pharma Industry Prospective
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What is CSRC from a Pharma Industry Prospective?



An optimized public health focused venue to collaboratively interact with key constituencies:

- To focus on cardiac safety issues during the new medical product development process
- To share knowledge to improve and/ or enhance the evaluative sciences (preclinical & clinical)
- Opportunity for Quality, Speed and Value (QSV) in medicinal product development

How Does CSRC Work?



Under the “Memorandum of Understanding” between FDA and Duke:

- Involves industry, academics, and regulators
- Membership Charter describes the expectations and process by which individuals, companies and organizations can focus and contribute to cardiac safety and new medicinal product development

Why Pharma Industry Has Joined Together?



Public Health/ Patient Safety Focus

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Why Pharma Industry Has Joined Together?, continued



- Cardiac Safety:
 - Enhance scientific and clinical understanding and application in clinical assessments and new medicinal product development:
 - Creation of cardiac risk ECG library and explore new ECG biomarkers and reference standards
 - Create and explore new non-ECG related cardiac safety biomarkers
 - Develop additional research and regulatory evaluation tools to facilitate clinical decision-making and future medical product development with a focus on public health
 - Develop nomenclature and tools to facilitate the development of standards evidence base for new diagnostics and assessment tools that are widely available to researchers, clinicians and patients

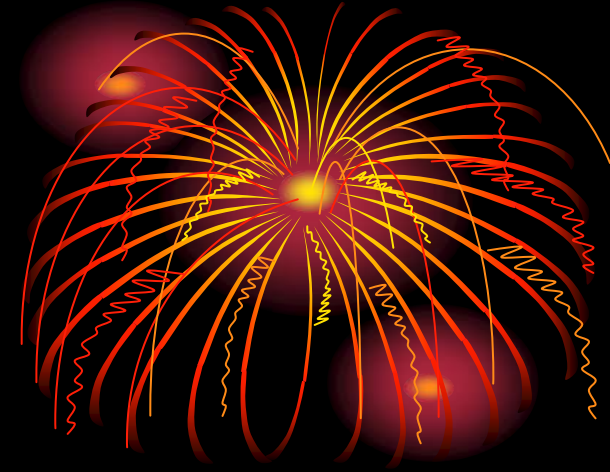
Why Pharma Industry Has Joined Together?, continued



- **Collaboration**

- Representatives from individuals, academia, industry, professional societies, trade organizations, CROs, core labs, patient advocate groups, regulatory agencies, etc.
 - without geographic or regional restrictions
- Broad participation within and through various areas and venues (i.e. governance, committees, think tanks, projects, white papers, etc.)

Why CSRC?



- Optimal use of time, talent and \$\$\$\$\$ to have a “voice” to enhance patient safety and promote the development of new medicines, devices and tools of assessment.
- Good for the patient—Good for science—Good for business.

Thank You!

