



PASSION CAD: SAFE PCI STEMI for Seniors *FDA Comments*

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PASSION CAD: SAFE PCI STEMI for Seniors

- Address questions of public health importance
 - Key constituent population: The elderly
 - Radial artery access
 - PCI with a candidate DES for STEMI
 - Guided complete revascularization vs. culprit vessel only
- Consistent with FDA's interest in efficient clinical trials and use of clinical data
- Opportunity to collect safety and effectiveness data to support expanded indications for use
- IDE regulations provide for enhanced protection for clinical study participants

The 8 A's of an IDE Embedded in an Ongoing Registry

- **A**greement to participate: Informed consent
- **A**ccountability of study subjects: Minimize subject withdrawals & lost to follow-up
- **A**ccumulation of data: Capture relevant events and minimize missing information
- **A**ccuracy of data collection and recording
- **A**djudication of events
- **A**nalysis of data using pre-specified event definitions, endpoints, a SAP, and core labs (when needed)
- **A**uditing & monitoring of study data and study progress
- **A**ccess to data (e.g., investigators, industry, FDA, CMS)