

Non-clinical Cardiac Troponins: A view from FDA/CDER

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- The views and opinions expressed are those of the presenter and do not necessarily represent the views of the FDA.

Current CDER Use

- Situational
 - Case by case
 - Preclinical signal : further work up preclinically
 - Preclinical signal: add to clinical monitoring
 - Class of drug
 - Previous experience with the class
 - Previous experience with the mechanism
- The usual rules apply
 - What's the indication
 - What's the (apparent) margin of safety
 - What's the rest of the story

Concerns expressed so far for preclinical use of cTn

- How do we interpret the results ?
 - Assay issues
 - Study design
 - Mechanistic
- What do we do with events that are biochemically detectable but clinically insignificant?
- Personal concern: educated use on both sides

What about future use? Some possibilities:

1. General use, include this as a standard feature in clinical chemistry panels
2. Tier II assay, after a signal is detected
3. Create a new paradigm for cardiovascular safety testing
4. Create a new paradigm for general toxicity testing