

Resource Summary Report

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O'Brien Reagan York and Jacobsen Drug-induced Cardiotoxicity Biomarkers

RRID:SCR_003717

Type: Tool

Proper Citation

O'Brien Reagan York and Jacobsen Drug-induced Cardiotoxicity Biomarkers
(RRID:SCR_003717)

Resource Information

URL:

<http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualification>

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Description: Serum / plasma biomarkers, Cardiac troponins T (cTnT) and I (cTnI), in safety assessment studies for rats, dogs, and monkeys are qualified biomarkers for the following contexts of use: # When there is previous indication of cardiac structural damage with a particular drug, cardiac troponin testing can help estimate a lowest toxic dose or a highest non-toxic dose to help choose doses for human testing. In this case, cardiac troponins may serve as a clinical chemistry correlate to the histology. For example, in a safety assessment study, lower doses without increases in cardiac troponins may be used to support a no observed effect level (NOEL) identified by histology. # When there is known cardiac structural damage with a particular pharmacologic class of a drug and histopathologic analyses do not reveal structural damage, circulating cardiac troponins may be used to support or refute the inference of low cardiotoxic potential. # When unexpected cardiac structural toxicity is found in a nonclinical study, the retroactive (reflex) examination of serum or plasma from that study for cardiac troponins can be used to help determine a no observed adverse effect level (NOAEL) or lowest observed adverse effect level (LOAEL). The results of this testing may support inclusion of cardiac troponin testing in subsequent safety assessment studies.

Abbreviations: O'Brien et al Cardiotoxicity Biomarkers

Synonyms: O'Brien Reagan York and Jacobsen Drug-induced Cardiotoxicity Biomarkers

Resource Type: data or information resource, narrative resource, standard specification

Keywords: serum, plasma, biomarker, cardiac troponins t, cardiac troponins i, heart, biomarker, drug development, drug, gold standard

Related Condition: Cardiotoxicity, Drug-induced Cardiotoxicity

Availability: Public

Resource Name: O'Brien Reagan York and Jacobsen Drug-induced Cardiotoxicity Biomarkers

Resource ID: SCR_003717

Alternate IDs: nlx_157893

Record Creation Time: 20220129T080220+0000

Record Last Update: 20260729T044050+0000

Ratings and Alerts

No rating or validation information has been found for O'Brien Reagan York and Jacobsen Drug-induced Cardiotoxicity Biomarkers.

No alerts have been found for O'Brien Reagan York and Jacobsen Drug-induced Cardiotoxicity Biomarkers.

Data and Source Information

Source: [SciCrunch Registry](#)

Usage and Citation Metrics

We have not found any literature mentions for this resource.