

Resource Summary Report

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ILSI HESI Drug-induced Nephrotoxicity Biomarkers

RRID:SCR_003716

Type: Tool

Proper Citation

ILSI HESI Drug-induced Nephrotoxicity Biomarkers (RRID:SCR_003716)

Resource Information

URL:

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

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Description: Urinary kidney biomarkers, Clusterin and Renal Papillary Antigen-1 (RPA-1), that sponsors may use to determine more conservative NOAELs for estimating starting doses in the initial human clinical trial of a drug that displays nonclinical nephrotoxicity as determined by histopathology. When tested with a limited number of nephrotoxic compounds, the Receiver Operating Characteristic (ROC) analyses showed that urinary clusterin and renal papillary antigen-1 (RPA-1) have better sensitivity and specificity than BUN and creatinine for the detection of specific kidney pathologies in male rats. Clusterin and RPA-1 provide additional and complementary information to BUN, serum creatinine (sCr), and histopathology for the detection of acute drug-induced nephrotoxicity in safety assessment studies.

Abbreviations: HESI Nephrotoxicity Biomarkers

Synonyms: HESI Drug-induced Nephrotoxicity Biomarkers, ILSI / HESI Nephrotoxicity Working Group Drug-induced Nephrotoxicity Biomarkers, International Life Sciences Institute / Health and Environmental Sciences Institute Nephrotoxicity Working Group Drug-induced Nephrotoxicity Biomarkers

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

Keywords: biomarker, drug development, drug, urinary, urinary biomarker, gold standard, clusterin, renal papillary antigen, kidney, gold standard

Related Condition: Nephrotoxicity, Drug-induced nephrotoxicity

Availability: Public

Resource Name: ILSI HESI Drug-induced Nephrotoxicity Biomarkers

Resource ID: SCR_003716

Alternate IDs: nlx_157892

Record Creation Time: 20220129T080220+0000

Record Last Update: 20260905T132506+0000

Ratings and Alerts

No rating or validation information has been found for ILSI HESI Drug-induced Nephrotoxicity Biomarkers.

No alerts have been found for ILSI HESI Drug-induced Nephrotoxicity Biomarkers.

Data and Source Information

Source: [SciCrunch Registry](#)

Usage and Citation Metrics

We have not found any literature mentions for this resource.