

Resource Summary Report

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Drug Development Tools Qualification Programs

RRID:SCR_003714

Type: Tool

Proper Citation

Drug Development Tools Qualification Programs (RRID:SCR_003714)

Resource Information

URL:

<http://www.fda.gov/drugs/developmentapprovalprocess/drugdevelopmenttoolsqualificationprogram/default.aspx>

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Description: To support Drug Development Tools development efforts, FDA established qualification programs for animal models for use under Animal Rule, biomarkers, and clinical outcome assessments. DDTs are methods, materials, or measures that have potential to facilitate drug development. Examples of DDTs may include, but are not limited to biomarker² used for clinical trial enrichment, clinical outcome assessment used to evaluate clinical benefit, and animal model used for efficacy testing of medical countermeasures under regulations commonly referred to as Animal Rule³.

Abbreviations: DDT Qualification Programs

Synonyms: Drug Development Tools (DDT) Qualification Programs

Resource Type: data or information resource, portal

Keywords: Drug¹ Development Tools, FDA established qualification programs, animal models for use under Animal Rule, gold standard

Funding:

Availability: Public

Resource Name: Drug Development Tools Qualification Programs

Resource ID: SCR_003714

Alternate IDs: nlx_157888

Record Creation Time: 20220129T080220+0000

Record Last Update: 20250523T054338+0000

Ratings and Alerts

No rating or validation information has been found for Drug Development Tools Qualification Programs.

No alerts have been found for Drug Development Tools Qualification Programs.

Data and Source Information

Source: [SciCrunch Registry](#)

Usage and Citation Metrics

We found 1 mentions in open access literature.

Listed below are recent publications. The full list is available at [FDI Lab - SciCrunch.org](#).

Mol PGM, et al. (2018) Precision medicine in diabetes and diabetic kidney disease: Regulatory considerations. Diabetes, obesity & metabolism, 20 Suppl 3(Suppl Suppl 3), 19.