Resource Summary Report

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Critical Path to TB Drug Regimens

RRID:SCR_003698
Type: Tool

Proper Citation

Critical Path to TB Drug Regimens (RRID:SCR_003698)

Resource Information

URL: http://cptrinitiative.org/

Proper Citation: Critical Path to TB Drug Regimens (RRID:SCR_003698)

Description: A collaboration of international pharmaceutical companies, public health experts, civil society organizations, and U.S., European, and other regulatory authorities to speed the development of new and improved drug regimens for tuberculosis (TB). Its goals include creating innovative tools, including TB data standards and databases. The Initiative is built around four operating arms: Regulatory Science Consortium, Drug Development Coalition, Research Resources Group, and Drug Susceptibility Testing Group. The focus of the consortium is to: * Develop and integrate data standards * Qualify biomarkers through the Food and Drug Administration (FDA) / European Medicines Authority (EMA) * Develop quantitative disease progression (natural history) models * Create disease response metrics, develop target product profiles and supporting assays, and * Develop new pharmacokinetic/dynamic measures of drug interactions Accomplishments include: * Engaged the FDA, which has released updated regulatory guide-lines for developing new TB drug regimens with efforts to create a more favorable environment for combination regimen development * TB Alliance launched the first-ever clinical trial of a novel combination drug regimen for TB, validating the approach to regimen development set forth by CPTR, and is moving to a phase III clinical trial named STAND. * Developed and published TB data standards in collaboration with the Clinical Data Interchange Standards Consortium (CDISC). * Expanded scope to include the CPTR Rapid Drug Susceptibility Testing (RDST) Consortium and an expanded Modeling and Simulation development program. * Pursued several regulatory pathways with the FDA for the Hollow Fiber System Model for TB (HFS-TB). * Submitted a dossier to the EMA on the HFS-TB for qualification opinion consideration. * Submitted a "briefing book" to the FDA via the pre-IND process to review CPTR's data analysis plan and data inventory for liquid culture, with emphasis on time-to-positivity, as a quantitative measure of long-term outcome. * Initiated planning to develop a database supporting the RDST Consortium's goal to develop a rapid TB drug susceptibility test.

Abbreviations: CPTB

Synonyms: Critical Path to Tuberculosis Drug Regimens

Resource Type: consortium, data or information resource, international standard specification, portal, narrative resource, standard specification, organization portal

Keywords: drug development, product development, drug, consortium, drug regimen, biomarker, drug sensitive, drug resistant, pamz, clinical trial, treatment, database, hollow fiber system model for tb, diagnostic assay, drug susceptibility test, regulatory guideline

Funding: Bill and Melinda Gates Foundation

Resource Name: Critical Path to TB Drug Regimens

Resource ID: SCR_003698

Alternate IDs: nlx_157981

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Record Last Update: 20260801T190216+0000

Ratings and Alerts

No rating or validation information has been found for Critical Path to TB Drug Regimens.

No alerts have been found for Critical Path to TB Drug Regimens.

Data and Source Information

Source: SciCrunch Registry

Usage and Citation Metrics

We found 2 mentions in open access literature.

Listed below are recent publications. The full list is available at T1D .

Magombedze G, et al. (2021) Bacterial load slopes represent biomarkers of tuberculosis therapy success, failure, and relapse. Communications biology, 4(1), 664.

Bonnett LJ, et al. (2018) Quality of reporting of outcomes in phase III studies of pulmonary tuberculosis: a systematic review. Trials, 19(1), 134.