

Request for Records Disposition Authority

Records Schedule Number DAA-0088-2018-0003

Schedule Status Approved

Agency or Establishment Food and Drug Administration

Record Group / Scheduling Group Records of the Food and Drug Administration

Records Schedule applies to Major Subdivision

Major Subdivision Center for Drug Evaluation and Research

Schedule Subject The Drug Development Tool (DDT) Qualification Programs

Internal agency concurrences will be provided No

Background Information

The Drug Development Tool (DDT) Qualification Programs allow CDER to work with submitters to guide them as they develop or refine a DDT for a specific context of use. CDER then will rigorously evaluate the submission for use in the regulatory process. Qualifying a DDT will allow sponsors to use the DDT in the qualified context of use during drug development without requesting that CDER reconsider and reconfirm the suitability of the DDT for the qualified context of use.

Item Count

Number of Total Disposition Items	Number of Permanent Disposition Items	Number of Temporary Disposition Items	Number of Withdrawn Disposition Items
1	0	1	0

GAO Approval

Outline of Records Schedule Items for DAA-0088-2018-0003

Sequence Number	
1	The Drug Development Tool (DDT) Qualification Program
1.1	The Drug Development Tool (DDT) Qualification Program Disposition Authority Number: DAA-0088-2018-0003-0001

Records Schedule Items

Sequence Number	
1	The Drug Development Tool (DDT) Qualification Program
1.1	The Drug Development Tool (DDT) Qualification Program
	Disposition Authority Number DAA-0088-2018-0003-0001
	<p>The Drug Development Tool (DDT) Qualification Programs allow CDER to work with submitters to guide them as they develop or refine a DDT for a specific context of use. CDER then will rigorously evaluate the submission for use in the regulatory process. Qualifying a DDT will allow sponsors to use the DDT in the qualified context of use during drug development without requesting that CDER reconsider and reconfirm the suitability of the DDT for the qualified context of use. Records include requestor submissions (e.g., full qualification package, letter of intent, qualification plan, supplements) clinical and nonclinical study reports, meeting packages, datasets, meeting summaries, slide presentations, FDA analysis reports, correspondence with requestors, submission tracking information, FDA response letters, and other related records.</p>
	Final Disposition Temporary
	Item Status Active
	Is this item media neutral? Yes
	Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? Yes
	Do any of the records covered by this item exist as structured electronic data? Yes
	Disposition Instruction
	Cutoff Instruction Records related to proposed and qualified projects will be retained until the project status changes to discontinued, inactivated, terminated, or qualification is withdrawn.
	Transfer to Inactive Storage N/A
	Retention Period Destroy 30 year(s) after project is discontinued, inactivated, terminated, or qualification is withdrawn.
	Additional Information
	GAO Approval Not Required

Agency Certification

I hereby certify that I am authorized to act for this agency in matters pertaining to the disposition of its records and that the records proposed for disposal in this schedule are not now needed for the business of the agency or will not be needed after the retention periods specified.

Signatory Information

Date	Action	By	Title	Organization
10/01/2018	Certify	Garland Hodges	Management Analyst	Food and Drug Administration - OC
11/07/2018	Return for Revision	Carly Docca	Archives Specialist	National Archives and Records Administration - ACRA
12/06/2018	Return for Revision	Carly Docca	Archives Specialist	National Archives and Records Administration - ACRA
12/07/2018	Submit For Certification	Garland Hodges	Management Analyst	Food and Drug Administration - OC
12/14/2018	Certify	Garland Hodges	Management Analyst	Food and Drug Administration - OC
08/06/2019	Submit for Concurrence	Carly Docca	Archives Specialist	National Archives and Records Administration - ACRA
08/07/2019	Concur	Margaret Hawkins	Director of Records Management Services	National Records Management Program - ACNR Records Management Services
08/13/2019	Concur	Laurence Brewer	Chief Records Officer	National Records and Archives Administration - National Records and Archives Administration
08/15/2019	Approve	David Ferriero	Archivist of the United States	Office of the Archivist - Office of the Archivist