

Therapeutic Area (Disease/Domain) Data Standards Prioritization

This document is a tabular representation of the data graphically shown in the Roadmap for Development of Priority Therapeutic Area (TA) Standards document. It has been developed so additional information can be easily added periodically to communicate information regarding TA development projects.

Number	TA	Roadmap Grouping ¹	Status ⁶	Start Date	Added to List ²	Removed from List ²	Tier ³	Stage ^{4,5}
1	Alzheimer's	1	Published				Tier 1	Public Release, v2.0
2	Cardiovascular (CV)	1	Published				Tier 1	Public Release, v1.0 Provisional
3	CV Imaging (Echo)	1	Started		version 1			CFAST: Development
4	Pain	1	Published				Tier 1	Public Release, v1.1 Provisional
5	Parkinson's	1	Published				Tier 1	Public Release, v1.0 Provisional
6	Polycystic Kidney Disease	1	Published				Tier 1	Public Release, v1.0
7	Schizophrenia	1	Published				Tier 1	Public Release, v1.0 Provisional
8	Tuberculosis	1	Published				Tier 1	Public Release, v2.0
9	Virology	1	Published		version 1			Public Release, v2.0
10	Diabetes (previously Anti-diabetic agents)	2	Published	Q3 FY13			Tier 1	Public Release, v1.0 Provisional
11	Irritable bowel syndrome (IBD): Crohn's disease & Ulcerative colitis	2	Started	Q3 FY14	version 4	version 1	Tier 1	FDA: Requirements Definition
12	Major Depressive Disorder	2	Published	Q4 FY12			Tier 2	Public Release, v1.0
13	Complicated Urinary Tract Infections (cUTI)	2	Started	Q2 FY14			Tier 1	FDA: Requirements Definition
14	Acne	3	Started	Q1 FY13			Tier 1	FDA: Requirements Definition
15	Prevention of Pregnancy	3	Started	Q3 FY14			Tier 1	FDA: Requirements Definition
16	Rheumatoid Arthritis (RA)	3	Published	Q1 FY14			Tier 1	Public Release, v1.0
17	Complicated Skin and Skin Structure Infections (ABSSSI) (formerly Infection of Skin and/or Subcutaneous Tissue)	4	Started	FY15			Tier 1	FDA: Requirements Definition; CFAST: Proposed
18	QT Studies	4	Published	Q4 FY13			Tier 1	Public Release, v1.0 Provisional
19	Solid Organ Transplantation - Kidney	4	Published	Q1 FY14			Tier 1	Public Release, v1.0

Number	TA	Roadmap Grouping ¹	Status ⁶	Start Date	Added to List ²	Removed from List ²	Tier ³	Stage ^{4,5}
20	Influenza	5	Published	Q1 FY14			Tier 2	Public Release, v1.0 Provisional
21	Treatment of Postmenopausal Osteoporosis	5	Started	Q2 FY14			Tier 1	FDA: Requirements Definition
22	Anticonvulsants	6	Started	Q2 FY14			Tier 2	FDA: Requirements Definition
23	Dyslipidemia (formerly Lipid-altering Drug Groups)	6	Published	Q1 FY13			Tier 2	Public Release, v1.0 Provisional
24	Oncology - Breast	6	Published	Q2 FY14	version 5			Public Release, v1.0
25	Asthma	7	Published	Q1 FY13			Tier 2	Public Release, v1.0 Provisional
26	Bipolar Disorder	7	Started	Q4 FY14			Tier 2	Duke University: Development; CFAST: Proposed
27	Clostridium Difficile associated Diarrhea (formerly Clostridium Difficile Colitis)	7	Started	FY15			Tier 2	FDA: Requirements Definition; CFAST: Development
28	Muscular Dystrophy	7	Started	Q4 FY14	version 5			FDA: Requirements Definition; CFAST: Proposed
29	Oncology - Prostate	8	Started	Q4 FY14	version 5			FDA: Requirements Definition; CFAST: Development
30	Chemotherapy-induced Nausea and Vomiting	8	Started	FY15			Tier 3	Research Triangle Institute: Requirements Definition
31	COPD	8	Published	Q4 FY14			Tier 3	Public Release, v1.0 Provisional
32	Complicated Intra-Abdominal Infections (formerly Infectious Diseases of Abdomen)	8	Started	FY15			Tier 3	FDA: Requirements Definition
33	General Anxiety Disorder	9	Started	Q4 FY14			Tier 3	Duke University: Development; CFAST: Proposed
34	Treatment of Hepatitis C	9	Published	Q2 FY13			Tier 1	Public Release, v1.0 Provisional
35	Diabetic Nephropathy (also called Diabetic Kidney Disease)	9	Published	Q3 FY14			Tier 2	Public Release, v1.0
36	Attention Deficit Hyperactivity Disorder (ADHD)	9	Started	Q2 FY14			Tier 3	FDA: Requirements Definition
37	Treatment of Overactive Bladder	10	Started	Q1 FY13			Tier 2	FDA: Requirements Definition
38	Oncology - Colorectal	10	Started	FY15	version 5			FDA: Requirements Definition; CFAST: Development

Number	TA	Roadmap Grouping ¹	Status ⁶	Start Date	Added to List ²	Removed from List ²	Tier ³	Stage ^{4,5}
39	Oncology - Lung	10	Started	FY15	version 5			FDA: Requirements Definition; CFAST: Scoping
40	Oncology - Brain	10	Started		version 7			FDA: Requirements Definition
41	Anticoagulants for Atrial Fibrillation (formerly Atrial Fibrillation)	11	Started	Q2 FY14			Tier 3	FDA: Requirements Definition
42	Traumatic Brain Injury	11	Published	Q4 FY14			Tier 3	Public Release, v1.0
43	Psoriasis	12	Interest in 2018		version 6	version 4	Tier 1	CFAST: Proposed
44	Oncology – Cervical Cancer	12	Next Year		version 8			
45	Decompensated Congestive Heart Failure (CHF)	12	Interest in 2018				Tier 3	
46	Acute Kidney Injury	12	Interest in 2018					
47	Opioid Induced Constipation	13	Next Year		version 1			
48	Treatment of Hepatitis B	13	Next Year				Tier 3	
49	Tinea Pedis	13	Next Year				Tier 3	
50	Chronic Idiopathic Constipation	14	Next Year		version 1			
51	Treatment of HIV*	14	Started	2016			Tier 2	CFAST: Development
52	Prevention of HIV*	14	Started	2016			Tier 2	CFAST: Development
53	Treatment of Vasomotor Symptoms Due to Menopause	15	Interest in 2018				Tier 2	
54	Actinic Keratoses	15	Next Year				Tier 3	
55	Huntington's Disease	15	Started		version 10			CFAST: Development
Removed from List								
	Sedation	15			version 1	version 8		
	Pneumonia	6				version 6	Tier 2	
	Treatment of Cough	9				version 6	Tier 3	
	Bacterial Vaginosis	9				version 6	Tier 3	
	Aerosolized Antimicrobials for Cystic Fibrosis	10				version 6	Tier 3	
	Helicobacter Pylori Ulcer Disease	13				version 6	Tier 3	

Number	TA	Roadmap Grouping ¹	Status ⁶	Start Date	Added to List ²	Removed from List ²	Tier ³	Stage ^{4,5}
	Magnetic Resonance Imaging (MRI) Contrast Agent	6				version 6	Tier 3	
	Diagnostic Radiopharmaceutical	4				version 6	Tier 3	
	Treatment of Erectile Dysfunction	12				version 6	Tier 3	
	Hyperdynamic Lines	10				version 6	Tier 3	
	Recombinant Human Growth Hormone Products	14				version 6	Tier 3	
	Oncology: Time to Efficacy Event - other than overall survival (e.g., progression-free survival, disease-free survival, etc.)	2				version 5	Tier 1	With the availability of the SDTM Oncology domain models for Tumor Identification (TU), Tumor Results (TR) and Disease Response (RS) in SDTMIG v3.1.3 and later and the revised approach to develop the Oncology TA by body system (e.g., Oncology - Breast) this TA is being removed from the list.
	Oncology: Objective Tumor Response (including Complete Response, Partial Response etc.)	3				version 5	Tier 2	See note for previous item.
	Gastroesophageal Reflux Disease	2				version 4	Tier 2	
	Addiction					version 1	Tier 2	

* Detailed requirements are already defined

¹ Roadmap Grouping reflects the grouping of each TA as shown on the Roadmap for Development of Priority Therapeutic Area Standards document.

² FDA updates the TA list periodically based on feedback from the CDER Review Divisions. The version of this document where a TA was added or removed is shown here for tracking purposes.

³ Tier shows the original tier information assigned in November 2011 for historical tracking purposes. This was replaced by the information in the Roadmap Grouping column.

⁴ For Stage term definitions see Table 6 of the CDER Data Standards Strategy Action Plan available on the CDER Data Standards Program webpage. To see current progress for those listed with "CFAST: Development" or to see the list of "CFAST: Proposed", go to www.cdisc.org/therapeutic

⁵ Acronyms: Clinical Data Interchange Standards Consortium (CDISC), Coalition for the Advancement of Standards and Therapies (CFAST), Critical Path Institute

Number	TA	Roadmap Grouping ¹	Status ⁶	Start Date	Added to List ²	Removed from List ²	Tier ³	Stage ^{4,5}
--------	----	-------------------------------	---------------------	------------	----------------------------	--------------------------------	-------------------	----------------------

⁶ Status: Values include: Published; Started - work related to the TA has begun; Interest in 2018 - CDER is interested in a project for this TA in 2018; Next Year - CDER is interested in a project but not to start before 2019

The term “therapeutic area” also includes diagnostic and preventive areas. Some areas may represent a disease/domain area.

Note: To see the CFAST TA plan, go to <http://www.cdsc.org/therapeutic>

Initial Version, November 2011

version 1, 09-28-2012

version 2, 02-21-2013

version 3, 07-22-2013

version 4, 10-29-2013

version 5, 09-09-2014

version 6, 07-17-2015

version 7, 11-23-2015

version 8, 04-08-2016

version 9, 04-19-2016

version 10, 03-02-2018