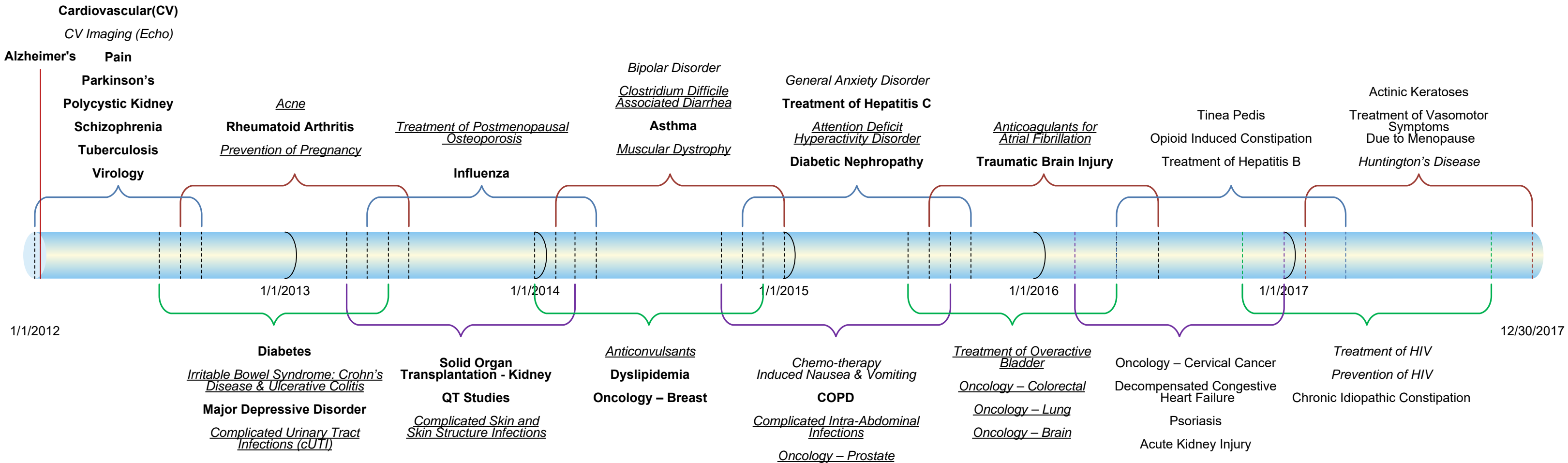# Therapeutic Area Data Standards Roadmap* (version 12, March 16, 2018)

This timeline, initially released in early 2012, illustrates therapeutic areas projects on a five (5) year timeline. A key assumption for therapeutic area standardization projects is that they are scoped to a 12-month project period, and that subsequent projects would build on the results. The therapeutic/disease areas are shown in priority groupings based on several factors including: projects already started, pipeline, FDA review division feedback. There are many factors affecting FDA and external stakeholders that impact project start order including: funds availability, subject matter expertise availability, and priority changes. The timeline will be updated periodically as progress, opportunity and additional information is available, but not reordered.

The information below is available in the Table of Priority Therapeutic Area Standards (PDF) available at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm287408.htm

Cardiovascular(CV)

CV Imaging (Echo)

Alzheimer's　　**Pain**

Parkinson's

Polycystic Kidney　　　　　　　　　　*Acne*　　　Actinic Keratoses

Schizophrenia　　**Rheumatoid Arthritis**　　*Treatment of Postmenopausal*　　　　Bipolar Disorder　　　General Anxiety Disorder　　　　　　　　　　Tinea Pedis　　Treatment of Vasomotor Symptoms

Tuberculosis　　*Prevention of Pregnancy*　　*Osteoporosis*　　*Clostridium Difficile Associated Diarrhea*　　**Treatment of Hepatitis C**　　*Anticoagulants for*　　Opioid Induced Constipation　　Due to Menopause

Virology　　　　　　　　　　　　　　　**Influenza**　　**Asthma**　　*Attention Deficit Hyperactivity Disorder*　　*Atrial Fibrillation*　　Treatment of Hepatitis B　　*Huntington's Disease*

　　　　　　　　　　　　　　　　　　　　　　　Muscular Dystrophy　　**Diabetic Nephropathy**　　**Traumatic Brain Injury**

1/1/2013　　　　　　　　　　1/1/2014　　　　　　　　　　1/1/2015　　　　　　　　　　1/1/2016　　　　　　　　　　1/1/2017

1/1/2012　　12/30/2017

Diabetes　　　　　　**Solid Organ Transplantation - Kidney**　　*Anticonvulsants*　　Chemo-therapy Induced Nausea & Vomiting　　*Treatment of Overactive Bladder*　　Oncology – Cervical Cancer　　*Treatment of HIV*

Irritable Bowel Syndrome: Crohn's Disease & Ulcerative Colitis　　**QT Studies**　　**Dyslipidemia**　　**COPD**　　*Oncology – Colorectal*　　Decompensated Congestive Heart Failure　　*Prevention of HIV*

Major Depressive Disorder　　*Complicated Skin and Skin Structure Infections*　　**Oncology – Breast**　　*Complicated Intra-Abdominal Infections*　　*Oncology – Lung*　　Psoriasis　　Chronic Idiopathic Constipation

Complicated Urinary Tract Infections (cUTI)　　　　　　　　　　　　　　　*Oncology – Prostate*　　*Oncology – Brain*　　Acute Kidney Injury

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

Legend:
Project started
FDA requirements definition
TA User Guide Published

Therapeutic Area Data Standards Roadmap Version History

Version 1	03-12-2012	Initial release
Version 2	05-11-2012	Added Cardiovascular (CV), Chronic Idiopathic Constipation, Opioid Induced Constipation, and Sedation to the revised priority list; removed Crohn's Disease, Irritable Bowel Syndrome, Addiction, and Ulcerative Colitis as of 02-01-2012
Version 3	09-28-2012	Updated TAs for projects that are started, edited introduction text, general formatting update
Version 4	07-26-2013	Updated TAs for projects that have commenced, added indicator for FDA planned projects (underlined TAs)
Version 5	08-05-2013	Updated introduction text
Version 6	10-29-2013	Updated TAs for projects that are started, removed Gastroesophageal Reflux Disease, added back Crohn's Disease and Ulcerative Colitis as of 10-25-2013, updated Anti-diabetic agents to Diabetes
Version 7	11-12-2014	• Updated Urinary Tract Infections (complicated) to Complicated Urinary Tract Infections (cUTI) • Removed Oncology: Objective Tumor Response and Oncology: Time to Efficacy Event (other than overall survival, etc.) • Added Muscular Dystrophy, Oncology – Breast, Oncology – Prostate, Oncology – Colorectal, and Oncology – Lung
Version 8	07-17-2015	• This timeline aligns with the Table of Priority Therapeutic Area Project Plan version 6 • Added Psoriasis and removed ten therapeutic areas (see table for complete list)
Version 9	11-23-2015	• Added new TA • Updated order of TAs to align with the TA Data Standards Prioritization table document
Version 10	04-08-2016	• Added Oncology – Cervical Cancer • Removed Sedation
Version 11	04-19-2016	• Added Acute Kidney Injury
Version 12	03-16-2018	Updated to reflect v10 of the Table of Priority Therapeutic Area Standards