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.

See 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

Parkinson's

Poly cystic Kidney

Schizophrenia

Tuberculosis

Virology

Acne

Rheumatoid Arthritis

Prevention of Pregnancy

Clostridium Difficile Colitis

Asthma

Muscular Dystrophy

Influenza

Atrial Fibrillation

Traumatic Brain Injury

Tinea Pedis

Opioid Induced Constipation

Tuberculosis

Virology

Diabetes

Irritable Bowel Syndrome, Crohn's

Major Depressive Disorder

Complicated Urinary Tract Infections (cUTI)

Solid Organ Transplantation

QT Studies

Dyslipidemia

Oncology – Breast

Chemo-therapy Induced Nausea & Vomiting

COPD

Complicated Intra-Abdominal Infections

Oncology – Prostate

Treatment of Ovarian Cancer

Oncology – Colorectal

Oncology – Lung

Acute Kidney Injury

Chronic Idiopathic Constipation

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

Legend:

Project commenced

FDA requirements definition

TA User Guide Published
<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Changes</th>
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<tbody>
<tr>
<td>1</td>
<td>03-12-2012</td>
<td>Initial release</td>
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<tr>
<td>2</td>
<td>05-11-2012</td>
<td>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</td>
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<td>3</td>
<td>09-28-2012</td>
<td>Updated TAs for projects that are started, edited introduction text, general formatting update</td>
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<td>4</td>
<td>07-26-2013</td>
<td>Updated TAs for projects that have commenced, added indicator for FDA planned projects (underlined TAs)</td>
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<td>08-05-2013</td>
<td>Updated introduction text</td>
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<td>6</td>
<td>10-29-2013</td>
<td>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</td>
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<td>7</td>
<td>11-12-2014</td>
<td>Updated Urinary Tract Infections (complicated) to Complicated Urinary Tract Infections (cUTI)</td>
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<td>Removed Oncology: Objective Tumor Response and Oncology: Time to Efficacy Event (other than overall survival, etc.)</td>
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<td>Added Muscular Dystrophy, Oncology – Breast, Oncology – Prostate, Oncology – Colorectal, and Oncology – Lung</td>
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<td>8</td>
<td>07-17-2015</td>
<td>This timeline aligns with the Table of Priority Therapeutic Area Project Plan version 6</td>
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<td>Added Psoriasis and removed ten therapeutic areas (see table for complete list)</td>
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<td>11-23-2015</td>
<td>Added new TA</td>
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<td>Updated order of TAs to align with the TA Data Standards Prioritization table document</td>
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<td>10</td>
<td>04-08-2016</td>
<td>Added Oncology – Cervical Cancer</td>
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<td>Removed Sedation</td>
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<td>11</td>
<td>04-19-2016</td>
<td>Added Acute Kidney Injury</td>
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