

Regulatory Approval Timeline of Active Immunotherapies

The clinical development of active immunotherapies has exploded in the last ten years. Checkpoint inhibitors, in particular PD-1 and PD-L1, have been integrated into standard-of-care across many cancer types. The [CRI Anna-Maria Kellen Clinical Accelerator](#) team has tracked the FDA approval timeline of active immunotherapies, noting both their increase in frequency and gradually expanding range of cancer types and stages.

Anti-PD-1/L1 Antibody Approvals by U.S. FDA

Timeline of Anti-PD-1/L1 Antibody Approvals by the FDA

Updated March 04, 2025

Sources: CRI IO Intelligence, FDA



Timeline of Anti-PD-1/L1 Antibody Approvals by the FDA

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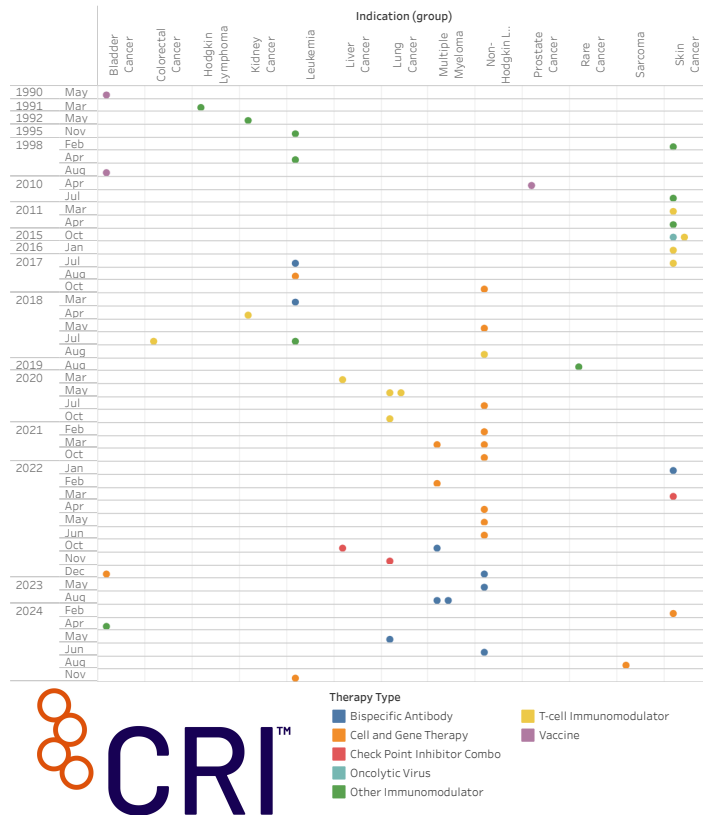
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Timeline of non-PD-1/L1 Immuno-Oncology Agent FDA Approvals

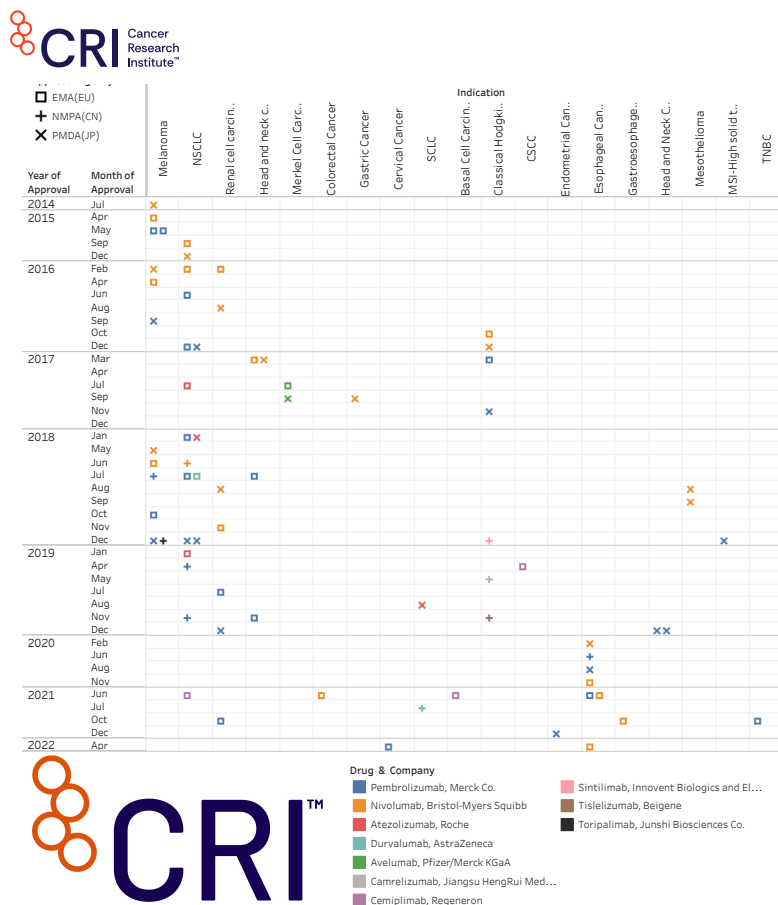
Updated November 08, 2024

Sources: CRI IO Intelligence, and FDA



Timeline of non-PD-1/PD-L1 Immuno-Oncology Agent Approvals by the FDA

Anti-PD-1/L1 Antibody Approvals by EU, Japan, and China



Timeline of Anti-PD-1/L1 Antibody Approvals by the European Medicines Agency (EMA) for the European Union (EU), National Medical Products Administration (NMPA) for China, and Pharmaceuticals and Medical Devices Agency (PMDA) for Japan.

More Resources for FDA Approval Timeline of Active Immunotherapies

Read about the [early results of the PRINCE clinical trial \(NCT03214250\)](#) on the CRI Immune to Cancer Blog.

Read IO Landscape Publications [→](#)

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Data Sources: Cancer Research Institute (CRI) analytics derive from public data sources, including trade news, company press releases, academic publications, FDA announcements, clinicaltrials.gov, and conference reports, and proprietary data sources including, but not limited to, GlobalData. The analytical algorithm and visualizations are developed by and therefore sole property of Cancer Research Institute.

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*Immunotherapy results may vary from patient to patient.

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