

2014 Regulatory Metrics Snapshots

© CIRS R&D Briefing 57

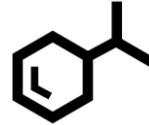
Approval in FDA 2014



FDA HAD A TOTAL OF 45 NASs APPROVED IN 2014, WITH A MEDIAN APPROVAL TIME OF 343 DAYS



15 BIOLOGIC NASs APPROVED IN 2014 WITH A MEDIAN APPROVAL TIME OF 334 DAYS



30 CHEMICAL NASs APPROVED IN 2014 WITH A MEDIAN APPROVAL TIME OF 362 DAYS

15 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2014 WITH A MEDIAN APPROVAL TIME OF 241 DAYS

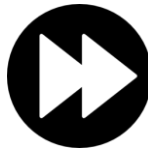


30 NASs IN OTHER THERAPY AREAS APPROVED IN 2014 WITH A MEDIAN APPROVAL TIME OF 365 DAYS



Type of Medicine

Designation and Review Type



26 EXPEDITED* NASs APPROVALS IN 2014 WITH A MEDIAN APPROVAL TIME OF 243 DAYS

21 ORPHAN NASs APPROVALS IN 2014 WITH A MEDIAN APPROVAL TIME OF 319 DAYS



19 STANDARD NAS APPROVALS IN 2014 WITH A MEDIAN APPROVAL TIME OF 456 DAYS

24 NON-ORPHAN NAS APPROVALS IN 2014 WITH A MEDIAN APPROVAL TIME OF 365 DAYS

Availability in FDA



87% OF THE NASs APPROVED IN 2014 BY FDA WERE APPROVED BY FDA FIRST OR WITHIN ONE MONTH OF THEIR FIRST APPROVAL IN ICH



13% OF THE NASs APPROVED IN 2014 BY FDA WERE APPROVED MORE THAN ONE MONTH FOLLOWING APPROVAL IN ANOTHER ICH COUNTRY

THE MEDIAN SUBMISSION GAP TO FDA FOR THESE NASs WAS 231 DAYS



*Note: Expedited review refers to FDA Priority Review