

# 2014 Regulatory Metrics Snapshots

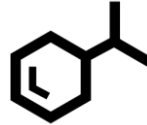
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## Approval in PMDA 2014

PMDA HAD A TOTAL OF 52 NASs APPROVED IN 2014, WITH A MEDIAN APPROVAL TIME OF 306 DAYS



12 BIOLOGIC NASs APPROVED IN 2014 WITH A MEDIAN APPROVAL TIME OF 300 DAYS



40 CHEMICAL NASs APPROVED IN 2014 WITH A MEDIAN APPROVAL TIME OF 321 DAYS

17 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2014 WITH A MEDIAN APPROVAL TIME OF 298 DAYS

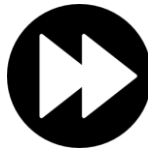


35 NASs IN OTHER THERAPY AREAS APPROVED IN 2014 WITH A MEDIAN APPROVAL TIME OF 332 DAYS



## Type of Medicine

## Designation and Review Type



26 EXPEDITED\* NASs APPROVALS IN 2014 WITH A MEDIAN APPROVAL TIME OF 275 DAYS

19 ORPHAN NASs APPROVALS IN 2014 WITH A MEDIAN APPROVAL TIME OF 270 DAYS



26 STANDARD NAS APPROVALS IN 2014 WITH A MEDIAN APPROVAL TIME OF 359 DAYS

33 NON-ORPHAN NAS APPROVALS IN 2014 WITH A MEDIAN APPROVAL TIME OF 343 DAYS

## Availability in PMDA



38% OF THE NASs APPROVED IN 2014 BY PMDA WERE APPROVED BY PMDA FIRST OR WITHIN ONE MONTH OF THEIR FIRST APPROVAL IN ICH



62% OF THE NASs APPROVED IN 2014 BY PMDA WERE APPROVED MORE THAN ONE MONTH FOLLOWING APPROVAL IN ANOTHER ICH COUNTRY

THE MEDIAN SUBMISSION GAP TO PMDA FOR THESE NASs WAS 867 DAYS



\*Note: Expedited review refers to PMDA Priority Review