

# 2014 Regulatory Metrics Snapshots

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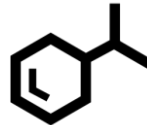
## Approval in EMA 2014



EMA HAD A TOTAL OF 30 NASs APPROVED IN 2014, WITH A MEDIAN APPROVAL TIME OF 418 DAYS\*



9 BIOLOGIC NASs APPROVED IN 2014 WITH A MEDIAN APPROVAL TIME OF 420 DAYS



21 CHEMICAL NASs APPROVED IN 2014 WITH A MEDIAN APPROVAL TIME OF 415 DAYS

11 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2014 WITH A MEDIAN APPROVAL TIME OF 442 DAYS

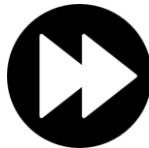


19 NASs IN OTHER THERAPY AREAS APPROVED IN 2014 WITH A MEDIAN APPROVAL TIME OF 415 DAYS



## Type of Medicine

## Designation and Review Type



4 EXPEDITED\*\* NAS APPROVALS IN 2014 WITH A MEDIAN APPROVAL TIME OF 264 DAYS

13 ORPHAN NASs APPROVALS IN 2014 WITH A MEDIAN APPROVAL TIME OF 469 DAYS,



26 STANDARD NAS APPROVALS IN 2014 WITH A MEDIAN APPROVAL TIME OF 432 DAYS

17 NON-ORPHAN NAS APPROVALS IN 2014 WITH A MEDIAN APPROVAL TIME OF 409 DAYS,

## Availability in EMA



37% OF THE NASs APPROVED IN 2014 BY EMA WERE APPROVED BY EMA FIRST OR WITHIN ONE MONTH OF THEIR FIRST APPROVAL IN ICH



63% OF THE NASs APPROVED IN 2014 BY EMA WERE APPROVED MORE THAN ONE MONTH FOLLOWING APPROVAL IN ANOTHER ICH COUNTRY

THE MEDIAN SUBMISSION GAP TO EMA FOR THESE NASs WAS 25 DAYS



Note: \*The EMA approval time includes the EU Commission time. \*\*Expedited review refers to EMA Accelerated Assessment