Drug Name Development Timeline

An outline of the timeline for application and implementation of a new United States Adopted Name (USAN), including preclinical, Investigational New Drug (IND), phases 1–3, new drug application or biologics licensing application, post-marketing, USAN application and initial review, USAN Council balloting, review of Council suggestion by the firm, international review and clearance, review of International Nonproprietary Name (INN) decision by the firm and Council, adoption and publication.

Drug Name Development Timeline

Preclinical

- Drug studies conducted in vitro and in animal models.
- Planned trade names may be filed, if known, with the United States Patent and Trademark Office and other trademark offices.
- Data about the mechanism of action and potential safety problems that could derail marketing are gathered.

Investigational New Drug

Firm obtains permission to conduct clinical studies in the United States from the FDA and receives an IND number.

Phase 1

- Small-scale safety studies conducted in healthy volunteers.
- Earliest time that U.S. firms may request a USAN or non-U.S. firms may request an INN.
Phase 2

- Small-scale efficacy studies in patients.
- Typical time for U.S. firms to apply for a USAN.
- Ballots sent to USAN Council for review.
- When firm and USAN Council reach consensus, USAN Program files to obtain an INN on behalf of the firm.
- Planned trade names may be filed for review by FDA, with supporting documentation.

Phase 3

- Large-scale efficacy and safety studies in humans.
- Many firms publish results of earlier clinical and preclinical studies and want the USAN at this time.
- USAN usually adopted and published.
- Non-U.S. firms with an INN apply for a USAN.

New Drug Application or Biologics Licensing Application

- Firm requests clearance from the FDA to market the drug.
- USAN required for packaging and labeling negotiations, promotional materials.
- United States Pharmacopeial Convention (USP) adds nomenclature information pertaining to dosage forms and delivery methods.
- Firm receives final approval of trade name from the FDA.

Post-marketing

- A USAN is required to market the drug in the U.S.
- Continued safety data on the drug and names are collected.
- Changes to generic or trade name require large-scale education of health care professionals, approval from the FDA.
- USP publishes monographs determining drug standards, titled with the USAN.

URL: https://www.ama-assn.org/about/united-states-adopted-names/drug-name-development-timeline
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