

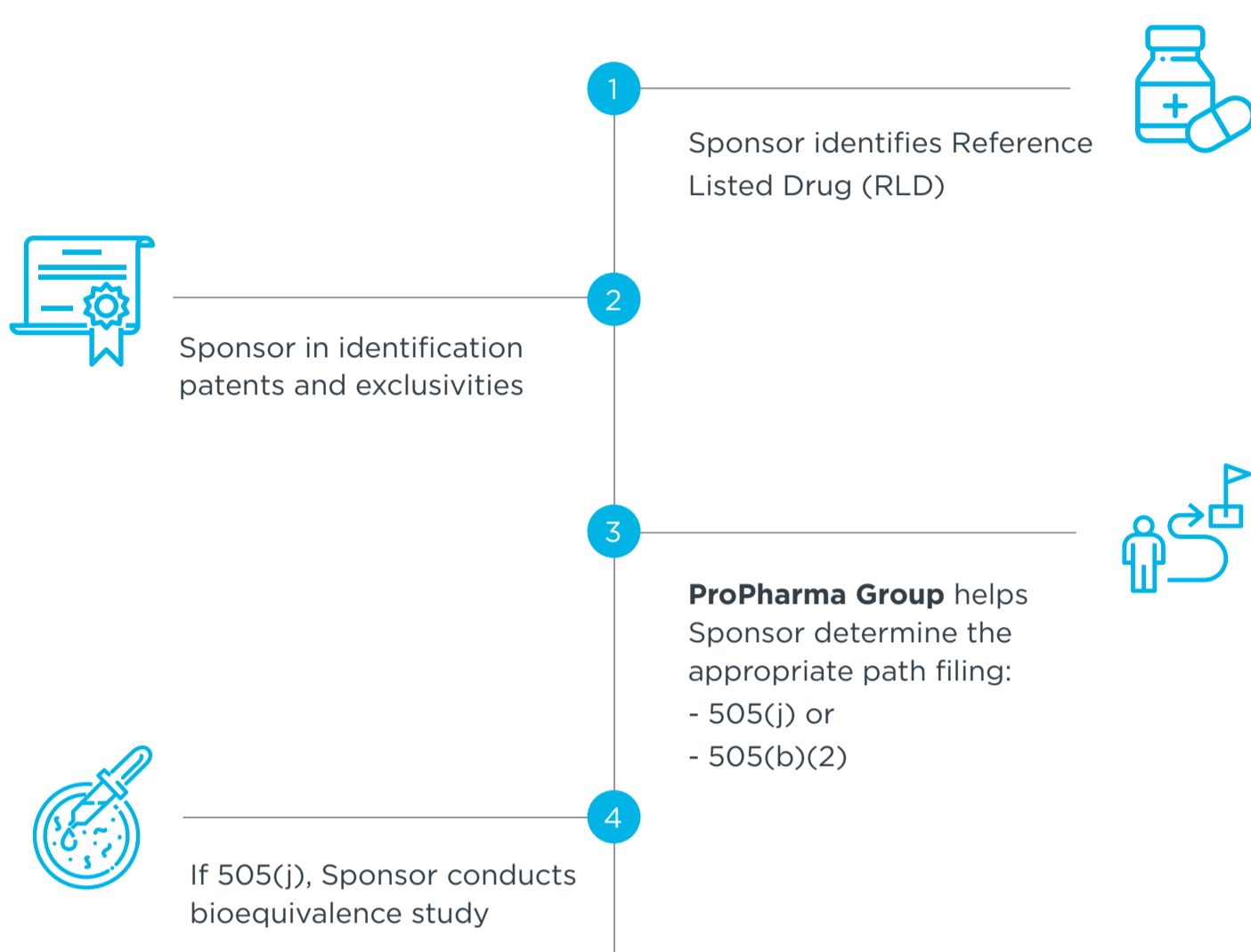
# How ProPharma Group Supports Clients Through The Generic Drug Application and Approval Process

## How does an ANDA Differ From an NDA?

- Abbreviated Application
- Typically, No Preclinical or Clinical Data Required
- Approval Based on Bioequivalence With Innovator Drug



## Pre-Filing Phase



## Is it a 505(j) or a 505(b)(2)?

(j) - same active ingredient, conditions of use, route of administration, dosage form, strength, and labeling (with certain permissible differences) as the RLD

(b)(2) - different active ingredient, condition of use, route of administration, dosage form, strength, or labeling than the RLD

## ProPharma Group

Supports clients in pre-filing activities, including:



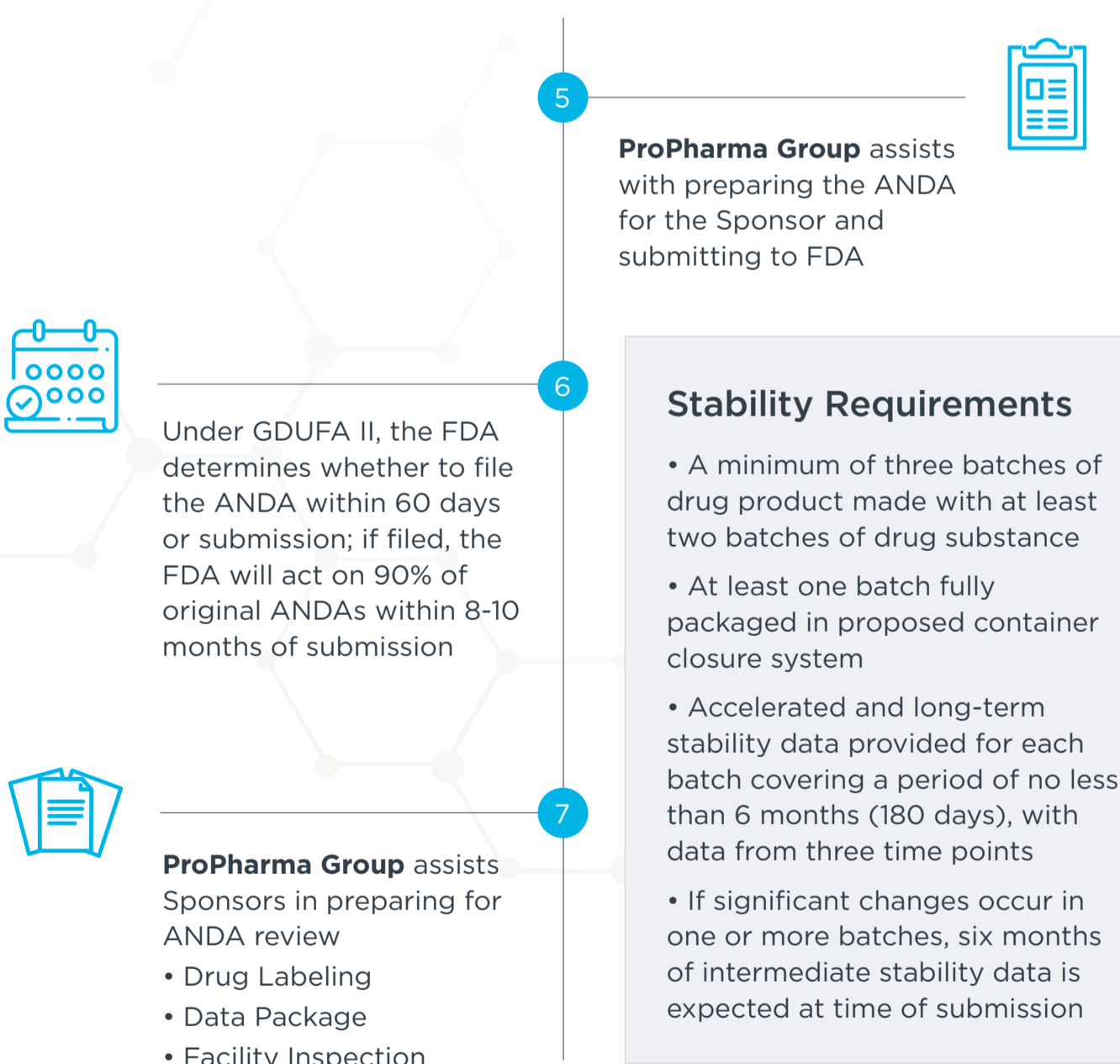
Controlled Correspondence



Pre-ANDA Meeting Requests



## Filing Phase



### Stability Requirements

- A minimum of three batches of drug product made with at least two batches of drug substance
- At least one batch fully packaged in proposed container closure system
- Accelerated and long-term stability data provided for each batch covering a period of no less than 6 months (180 days), with data from three time points
- If significant changes occur in one or more batches, six months of intermediate stability data is expected at time of submission



## Post-Approval



Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle.