Drug Development and Formulary Review

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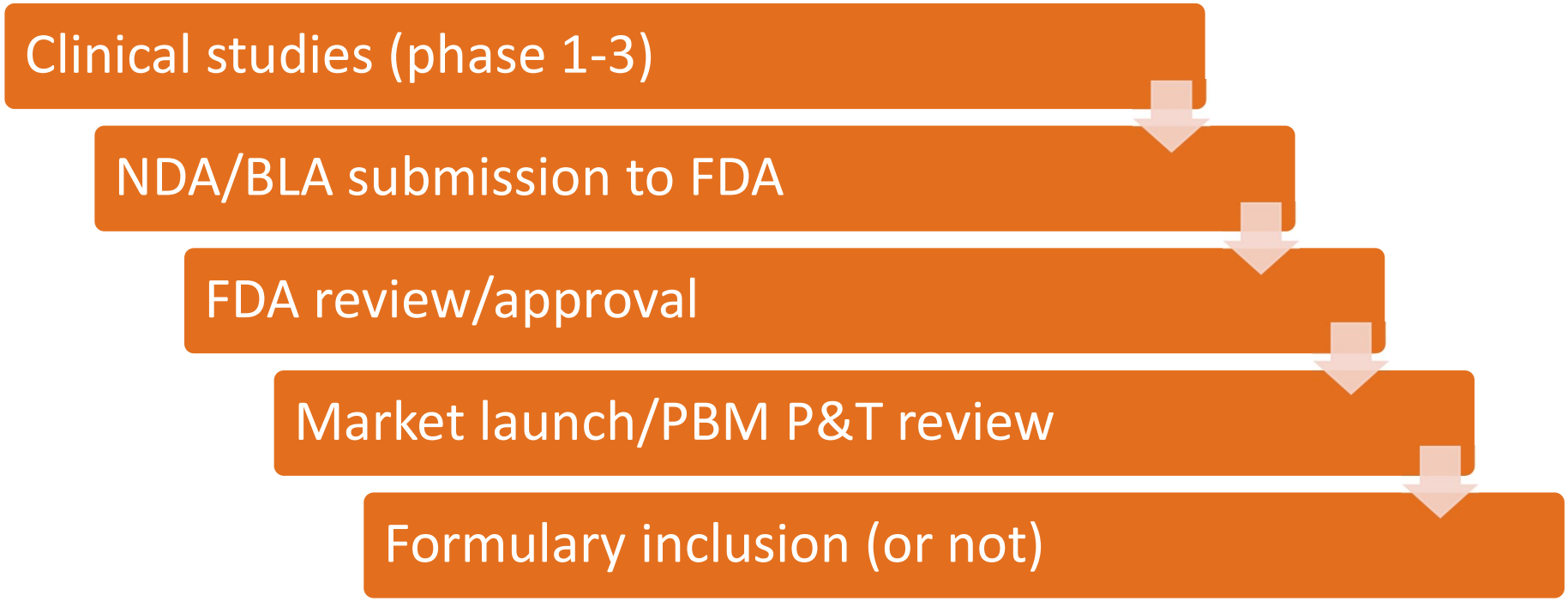
NAVITUS

Our business is personal

When will this be on formulary?



Clinical trials

- Start with pre-clinical lab and animal studies
- Phase I
  - Small studies – examine specific effects on humans
- Phase II
  - Finalize dosing
  - More focused endpoints/outcomes
- Phase III
  - The primary basis for regulatory submission and market review
  - Larger trials, important endpoints, often include a control group
  - Endpoints/design often dictated by FDA/regulatory guidance

I read an article that said……

- Fast track – products with unmet need/potential superiority to available products
  - Does not mean the product is approved or proven effective
- Breakthrough therapy – fast track + even more FDA meetings
  - Does not mean the product is approved or proven effective
- Orphan drug designation
  - Granted for specific drugs and is indication specific
    - Estimated < 200K patients in the US
    - Does not mean the product is approved or proven effective for that indication

https://www.fda.gov/patients/learn-about-drug-and-device-approvals/fast-track-breakthrough-therapy-accelerated-approval-priority-review

FDA approval

- FDA approval means the agency has determined that the product is both safe and effective for the indication granted
- After NDA or BLA is submitted – FDA has 60 days to accept
- If accepted – sets target date/deadline for approval decision
  - Generally 10 months after acceptance
  - 6 months for priority review
    - Significant enhancement or meets an unmet need for the treatment of a disease
    - Use of priority review voucher
- Accelerated review – unmet need
  - FDA may approve using surrogate endpoints
  - Requires a confirmatory study for continued/full approval

Market launch

- Following approval, the product can be released to the commercial market (available for pharmacies to order)
- Has official indication language from FDA
- Pricing becomes available/official
- Generally coincides with addition to large drug data companies (Medi-Span or FDB)

Formulary review

Pharmacy and Therapeutics Committee

- PBMs, health plans, health systems
- Generally comprised of prescribers and pharmacists
- Review data and discuss new drugs and drug classes
- Make final determinations on the clinical merits and where drugs fit into practice
- Depending on the organization – may also evaluate financial aspects, determine value, and make the final formulary decisions

Review timeline and process

- Different depending on the drug/situation
  - Available via exception before official review and formulary inclusion
- New molecular entity
  - Navitus P&T review ~6 months
- New indication for existing medication
  - Review at a subcommittee of P&T within 90 days
- Clinical review first
  - Navitus clinical P&T committee is available for clients to listen in
- Process is the same for everything, including mental health medication, clinical first, then financial

Examples

Rebates vs Lowest net cost

- Vumerity - branded agent similar to Tecfidera; slightly lower GI side effects
- Launched before Tecfidera generic at lower price and higher/similar rebates
- Tecfidera generic launch → massive price decrease
- Blocking Vumerity - higher net cost for short-period, but long-term cost per Rx ~$500 for majority generic use vs ~$2600 generic and Vumerity use

New approvals/uses

- Epidiolex – Rx, FDA-approved version of CBD approved for seizure disorders
- Ketamine – available IV and as vet med
  - New launch of nasal spray for depression
  - Medically administered product – reviewed at Navitus MAPC – added to MAP formulary with PA
- MDMA – NDA submitted to FDA
  - If granted priority review – decision in August 2024
  - Still need a change in DEA schedule too

Formulary development summary

- Make clinically appropriate decisions to have comprehensive coverage of member's disease states
- Maximize clinical outcomes while doing so at the lowest cost possible
- Clinically interchangeable products → pick lowest net cost
- Sometimes, clinically appropriate care might be more expensive than clinically inferior care
  - Ultimately not a good decision to pick inferior products – leads to increased costs in the long run and worse health