All About IPhO

Campbell University IPhO 2023-2024

Industry Pharmacists Organization

Student Involvement

- Every student who is involved with the VIP Case Project must be a **local Campbell IPhO Member** → $10/year

- IPhO National Member → $99/year
  - Includes complimentary MAPS Membership

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VIP CASE COMPETITION

Objectives of the VIP Case Competition

- Demonstrate the value of industry pharmacists
- Create a cohesive drug development plan, engaging several of the key functions where pharmacists most frequently contribute
- Provide diverse exposure to student pharmacists and allow them to explore new areas, think critically, and expand their network
- Provide student chapters with the opportunity to network and liaise with a current industry fellows and industry pharmacists.

Categories in the Case

- We are learning the process of bringing a drug to market
- An overarching goal in this competition is for participants to demonstrate the Value of Industry Pharmacists by highlighting the many key roles and contributions of industry pharmacists within the drug development process.
- We will cover in this project drug development from many perspectives:
    - Clinical sciences
    - Regulatory affairs
    - Commercial/marketing and medical affairs.

These key tenants may be expanded on by including other areas, such as health economics or clinical pharmacology, but are not mandated per competition requirements.

- Clinical development
- Regulatory affairs
- Medical affairs
- Marketing Research and Marketing/Commercial

Clinical Development

Main objective: Design a high-level clinical development plan (CDP) that supports your drug candidate through all four phases of clinical trials. You will need to generate sufficient safety and efficacy data to support approval from health authorities.

- What is the primary indication for which you are seeking US regulatory approval?
- As a clinical scientist, what types of clinical trials will you conduct, what are your safety and efficacy endpoints, and what are the objectives of each study? What is your patient population? What is the timeline?
- What difficulties do you foresee in the development process and what steps can you take to avoid them?
- What are other potential indications that can be investigated after approval?
- How will you engage and collaborate with the regulatory and medical affairs teams?

Regulatory Affairs

Main objective: Develop a US-focused regulatory strategy that will maximize your probability of success in achieving approval, while also utilizing regulatory pathways that will accelerate drug development and differentiation.

- Develop an IND or NDA filing strategy (i.e. what are your internal filing timelines to enable “First- Patient-In (FPI)” from summary document drafting to IND submission to IND clearance?) and what are the key messages of your IND package?
- How and when will health authority (FDA) interactions be utilized?
- Will you try to utilize any expedited programs? If so, which ones?
- What is your filing strategy? (i.e. indicate what pivotal and supportive trials will be used to support approval, indicate timelines in relation to the CDP, etc...)

Medical Affairs

Main objective: Develop evidence-based information regarding your company's drug, both pre and post-launch, to optimize product utilization. Establish and maintain relationships with prominent experts in the field.

- What resources or training will you provide to internal stakeholders?
- When will your company start disseminating medical information to external stakeholders?
- Who can receive off-label information about a medication?
- Who are your key opinion leaders (KOLs), and how would you go about identifying them nationally, regionally, and locally? What methods will you use to reach them?
- At what points during the drug development process will the company need to consult Medical Affairs for review?

Marketing Research and Marketing/Commercial

Main objective: Create a commercial strategy that will position your product as a highly valuable addition/option for the treatment of the disease and the features/benefits that will be used to promote your product in the marketplace.

- What is the competitive landscape? What are the unmet needs of physicians and patients that may need further exploration through conducting market research with these customers?
- Develop a brand strategy
    - Who is your target audience? (customer segmentation model, treatment naive, 2nd line dissatisfied vs satisfied, PCPs vs Specialists, allied healthcare professionals (IE. Pharmacists, nurses, PAs)
    - What are the customer's needs? Patients? Providers? Payers?
    - What customer insight would you use to drive your strategy?
    - What is the product positioning statement?
    - What are the core messages? Core messages are derived from clinical trials results, brand's features and benefits, and any competitive advantages
    - What key strategies and tactics will be used to advocate and promote your product? Including advertising and direct field force representation?
    - What materials/ special programs will you develop to support your product positioning and core messages?

Midpoint Submission November 12th

- Accounts for **15%** of the final case grade
- Must answer all questions in Competition Description for each subtopic
- Include in Midpoint Submission:
  - PowerPoint that provides a high-level overview of your drug's clinical development plan
  - answering all questions given in the Competition Description section
  - any questions, comments, or concerns regarding the competition
  - indicate if there is any risk to your chapter's completion of the competition deliverable by the due date.

Final Submission

- **February 25, 2023** → video + powerpoint
  - Video submission length is limited to 45 mins max
- This submission should provide details on your entire drug development plan, including the four areas discussed, and highlight the value of industry pharmacists in their many diverse roles.
- Final submission → 80%
- Midpoint evaluation → 15%
- Professionalism → 5%
  - (Completing the chapter competition evaluation survey at the time of the final submission is included the professionalism score.)
- Extra points will be provided for teams who submit earlier than the deadline (1 point if one week early, 2 points if two weeks early).

Winner announced in March 2023

Awards

First Place: $1000

Second Place: $500

Third Place: $250