Industry Pharmacists Organization

Value of Industry Pharmacists (VIP) Case Competition (2018-19)

Competition Guide
Version 3.0

This year's competition is sponsored by:

RevHealth

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Preamble

This guide shall serve as the main reference document for the Industry Pharmacists Organization (IPhO) Value of Industry Pharmacists (VIP) Case Competition. Details of the 2018-19 competition, including the case description, timelines, and resources, are embedded herein to support your chapter's success. Please refer to this document first for all questions you may have pertaining to competition details.

Best of luck. We hope this competition provides a broad, yet immersive learning experience to those choosing to participate.

IPhO - NFC Student Development Committee

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Introduction

What is the VIP Case Competition?

Drug development is a rigorous process involving many years of dedicated work from countless individuals. The objective of the IPhO VIP Case Competition is to distill down some of the core elements involved in drug development, ultimately producing a cohesive plan to bring a theoretical new molecular entity from 'bench to bedside'. 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.

In this annual competition, participating IPhO student chapters are asked to cover drug development from many perspectives, including 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 is not mandated per competition requirements.

As a resource, each chapter will be paired with a current industry fellow as a 'chapter partner' who can provide advice and guidance on ongoing project activities. Their experience should be actively leveraged throughout the duration of the project. We also encourage participating chapters to seek advice from appropriate school faculty and chapter advisors that have industry experience.

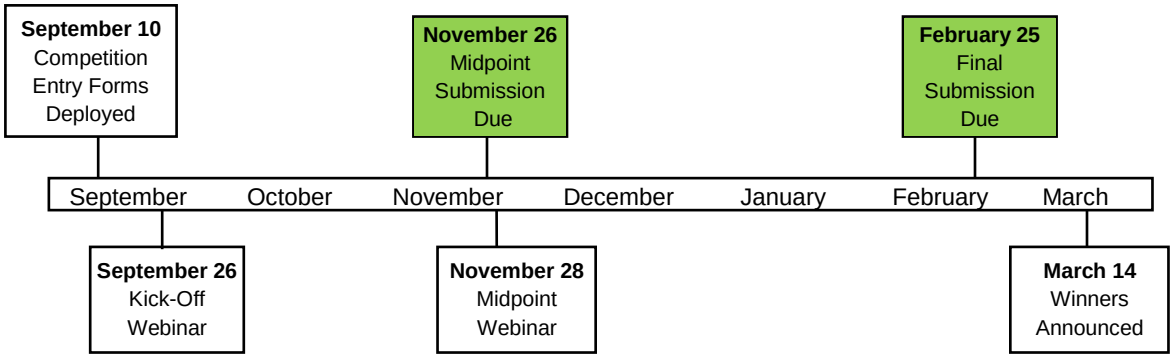
Purpose

The purpose of the VIP Case Competition is several-fold:

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

Deliverables and Timelines

Success in this competition is predicated on teamwork and consistency. Managing a project on this scale takes consistent efforts from several dedicated individuals. We recommend that work is spread across the duration of the competition and not be truncated into the periods prior to the submissions. Based on the size of your chapter and number of interested members, it may be best to organize into subgroups based on functional area. This divide-and-conquer approach has been successful for other chapters in the past and allowed for students to dig deeper in areas in which they may be more interested. Additionally, this allows work to be accomplished simultaneously and the larger group can come together, as needed, to share progress and updates. Below, please find the timeline for the competition. **Competition entry forms will be accepted between September 10th - 24th**. Deliverables are indicated below in green shading.



Please refer to the appendix for submission-specific details.

Midpoint Submission

Two submissions will be required for the VIP Case Competition: a midpoint submission and a final submission. The midpoint submission is due by **November 26, 2018 by 11:59 PM**. Submissions received after the due date will be docked 5% of their overall competition score per week, not to exceed the 30% attributed to this section (as stated in the next section). Please submit a document that provides a high-level overview of your drug's clinical development plan, answering **all** questions given in the Competition Description section. Also include any questions, comments, or concerns regarding the competition and indicate if there is any risk to your chapter's completion of the competition deliverable by the due date.

The focus of this submission is the four functional areas previously denoted (clinical development, regulatory affairs, commercial/marketing, and medical affairs). In addition, information on preclinical and drug-specific details, such as pre-clinical/clinical pharmacology, will be important to characterize your therapy in development.

Midpoint Submission Assessment

Your chapter's midpoint submission will be evaluated by members of the VIP Case Competition Committee and will account for 30% of your chapter's final score. There are a total of 30 questions asked in the Competition Description section. The Midpoint Submission will be graded for completion, with one point awarded for each *thoughtfully answered* question. Pre-clinical and drug-specific details will not be graded-on, but should be included in the Midpoint Submission.

Final Submission

The final submission is due **February 25, 2019 by 11:59 PM**. Please create a video submission of your team's presentation and submit both the video and PowerPoint presentation slide deck to ipho.vip.competition@gmail.com using the naming structure provided in the appendix.

This submission should provide details on your entire drug development plan, including the four areas discussed (clinical development, regulatory affairs, commercial/marketing, and medical affairs), and highlight the value of industry pharmacists in their many diverse roles. As before, information on preclinical and drug-specific details, such as pre-clinical/clinical pharmacology, will be important to characterize your therapy and inform your development strategy.

Although you are free to produce this video by any method, it may be easiest (and preferred) to record your presentation in PowerPoint and export it as a video. For more information, please refer to the appendix section.

Keep in mind that the aim of this case competition is to understand how the major drug development and commercialization functions work together. The more research your chapter performs, and the more professionals your chapter engages, the better you will understand the

independent activities of each functional area and how they work cross-functionally to successfully develop and market a drug.

Final Submission Assessment:

Please see the final assessment grading rubric, located in the appendix, for specific details. You will be graded primarily on your ability to demonstrate an appreciation for the different functional teams within industry and the value that an industry pharmacist brings to each role. Additional factors taken into consideration include: the depth/detail of your project, accuracy of subject matter covered, and quality of the video presentation. The final submission score will account for 70% of the final competition score, with the midpoint evaluation comprising the other 30%.

Submissions received after the due date will be docked 5% of their overall competition score. Due to the quick turnaround asked for by our judges, **any submission received after February 28th, 2019 at 11:59 PM EST will not be considered**.

The winning chapter will be selected by **March 14, 2019 at 11:59 pm.**

The winning chapter will be recognized at the **2019 IPhO Annual National Meeting**.

The winning chapters will receive monetary awards as follows:

- 1st Place - $1000
- 2nd Place - $500
- 3rd Place - $250

2018-19 VIP Case Competition Description

Prologue

Chronic pain is one of the most significant challenges in modern medicine, affecting at least 116 million U.S. adults and with an estimated economic burden of $560-635 billion per year.[1] *Shortcomings in currently available treatments for chronic pain is a critical issue. Moreover, the escalating opioid epidemic may make it more difficult for people who need opioids for pain control to obtain them. Innovative formulations that include both abuse deterrence and optimal pharmacokinetics are needed.*

Case Profile

Your pharmaceutical company has recently discovered a new molecular entity (NME), doxiretin, a partial mu-receptor agonist whose principal therapeutic action is analgesia. Modeling and simulation shows a favorable pharmacokinetic and pharmacodynamic profile. Preclinical studies conducted in rodents and non-rodents have demonstrated preclinical safety that is comparable with similar medications currently on the market; no concerning safety signals have been found. The early development teams have received approval from internal governance to develop a first-in-human clinical study protocol and file an investigational new drug (IND) with the FDA.

Your company now wants to plan ahead and determine all of the appropriate activities and steps that are needed to establish an innovative formulation, gain regulatory approval and bring this NME to patients. What needs to be accomplished to ensure this innovative therapy makes it to market and successfully reaches the patients who can benefit from it?

Please see below **objectives** and **questions** on each of the four key functional areas, as they will help guide the development of your plan. You are highly encouraged to ask more questions, be creative, and go past the scope of these guidelines. This is not a comprehensive list of all the questions that need answering in the final submission. Additionally, please be sure to **cover all the basic descriptive detail**; *name (both generic and brand, as appropriate), pharmacology considerations (PK/PD, mechanism of action, safety, toxicology, drug interactions, genomic considerations), target indication(s), dosing, administration, etc.*

Lastly, be sure to tie in the value of an industry pharmacist throughout the presentation and then, at the end, explain how pharmacists can be utilized more in pharmaceutical drug development.

[1] Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research. Washington (DC)2011.

Midpoint Submission

Key Functional Area Objectives and Questions

In the Midpoint Submission, as stated above, the bulleted questions included within each functional area should be answered to guide your thinking and research.

In the Final Submission, these bulleted questions do not have to be addressed verbatim. They are provided as a guide to successfully complete the main objectives.

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?
- How does a pharmacist's education and clinical experience contribute to success as a clinical scientist?

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 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 for a US-focused NDA? (i.e. indicate what pivotal and supportive trials will be used to support approval, indicate timelines in relation to the CDP, etc...)
- What advantage do pharmacists have in this role compared to other regulatory affairs professionals?

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.

- Who is on your Medical Affairs team?
- 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 **Doxiretin**?
- Who are your key opinion leaders (KOLs), and how would you go about approaching them?
- At what points during the drug development process will the company need to consult Medical Affairs for review?
- What is the value of a pharmacist in Medical Affairs?

Marketing Research & Marketing/Commercial

Main objective: Create a commercial strategy that will successfully differentiate your company's product in the marketplace, highlighting the brand's benefits and maximizing product uptake.

- What is the competitive landscape? Should you conduct market research to fill in the gaps?
- 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 competitive advantage, company's mission and values etc...
    - How will you market/advertise your brand utilizing media, printed materials, sales force, etc.?
    - What materials will you give your sales team to communicate these messages?
    - How will you use these messages in your marketing materials?
    - From a strategy perspective, how will you utilize landscape-based medical education? What will be your avenues/tactics for promotional marketing?
- How do industry pharmacists add value and fit into a role on a marketing team?

Value of Industry Pharmacists

Main objective: Showcase the variety of roles and experiences that industry pharmacists bring to the drug development process.

- What did you learn about the roles that pharmacists play?
- How do you think pharmacists could play a bigger role in drug development and commercialization?
- What aspects of a pharmacist's education and training help position them to be valued members within pharmaceutical industry?
- How can pharmacists better contribute to determining the value of a new medication?
- Be sure to include the role and value of the industry pharmacist in each section above.

Challenge Point

Drug development is not always a straightforward process. Each new molecular entity is accompanied by unique challenges that require critical thinking and creative solutions. Sometimes these challenges can be identified early in development, sometimes it's difficult to know they exist until they're present. Either way, the team needs to overcome these obstacles in order to execute a successful development plan.

As in real life, your chapter's drug development plan will have an element of the unknown (at least until the mid-point). This year, the VIP Case Competition is introducing a 'Challenge Point'. The 'Challenge Point' is a scenario or question that your chapter will have to tackle in order to prepare a successful development plan. The theme of the 'Challenge Point' will change every year and will be specific to the case. It may be related to one of the key functional areas (clinical sciences, regulatory, etc…) or it may involve some other aspect. **This 'Challenge Point' will be revealed at the midpoint webinar and is due as part of the final submission.**

We have provided below an example of a Challenge Point prompt:

(PLEASE NOTE THIS IS AN EXAMPLE AND DOES NOT REFLECT THE 2018-2019 CHALLENGE POINT TOPIC)

Several GLP-1 agonists are already on the market. Since the competition in this space is well-established, it is important to be able to demonstrate the value of your medication versus these other drugs in parameters beyond safety, efficacy, and traditional endpoints that are adequate for approval.

For your Challenge Point, please describe your company's 'ideal' Health Economics and Outcomes Research (HEOR) plan. Be sure to include any key activities or studies that should be implemented, accounting for both pre- and post-launch considerations. Other key considerations should include:

1. *What Real-World Evidence (RWE) would realistically support the additional value of your drug **beyond** comparative safety & efficacy relative to placebo & other already-approved products in the market? This includes but is not limited to:*
    a. *Pharmacoeconomic evidence (savings in cost, resources, etc.)*
    b. *Patient-focused evidence (quality-of-life, satisfaction, etc.)*
    c. *Provider-focused evidence (office visits, etc.)*
2. *What outcomes will you need to add into your development plan (Pre-Clinical to Phase 4, RWD, etc.) to generate the evidence mentioned earlier?*
3. *Who will you collaborate with, internally and externally on such RWE/HEOR activities?*

Now that you've identified what evidence would demonstrate the unique value of your product, how to generate that evidence, and who you would collaborate with, how do you plan to disseminate this evidence in a resource-effective manner?

Appendix

Frequently Asked Questions (FAQ)

Q. Who do I contact if I have questions not answered in the competition guide?
A. Please direct any additional questions to ipho.vip.competition@gmail.com.

Q. Who is my fellow chapter partner?
A. Fellow chapter partners will be assigned to each chapter when the competition begins. Chapters and fellows will be notified of their pairing within the first week after the kick-off webinar (to be held on September 26th).

Q. How many people are allowed per team?
A. You may include as many individuals as you would like per team. IPhO student members in any professional year are encouraged to participate.

Q. Can I work with others people besides my chapter partner (fellow), such as professors and industry professionals?
A. Yes! Please feel free to leverage your professional resources and network to their greatest extent to help your team in this competition.

Q. How much should our team focus on role of industry pharmacists vs the drug development plan for the final submission?
A. The drug development plan is the major deliverable for this competition. The role of industry pharmacists should be highlighted within each functional area (e.g. clinical development, regulatory affairs, etc…). For more specific information on how this will be assessed, please refer to the final submission rubric.

Q. The Midpoint Submission Assessment says it will be graded for completion based on *thoughtfully answered* questions. What does this mean?
A. This generally means that as long as your team put effort into answering the question, it will be counted as complete. Our goal with the midpoint submission is to make grading as objective as possible and full points should be very attainable for every chapter.

Submitting Midpoint and Final Materials

Please submit all materials to ipho.vip.competition@gmail.com using the following format:

Please title your email and the name of your submission materials (PDF, PPT, etc…) with the following structure (based on the materials being submitted):

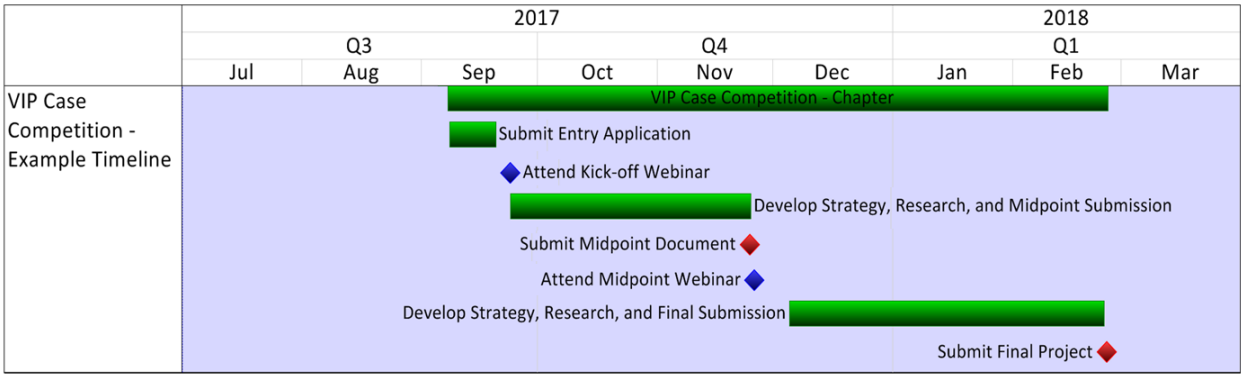
School Name_Midpoint Submission

OR

School Name_Final Submission

Example Timeline

This example timeline provides a loose structure to the periods within the VIP Case Competition time period. Please note that the **blue** diamonds represent webinars and the **red** diamonds represent submission deadlines.



Competition Resources

Functional Area Relevancy	Resource Name (With Link)	Resource Description
Clinical Development	ICH E6	A standard reference for conducting clinical trials within the scope of good clinical practice (GCP)
	FDA Guidance on Developing Analgesic Drugs	Very helpful guide to help shape the clinical development plan for your analgesic program
	Clinical Research Overview	High-level overview of clinical research process to bring a new drug to market
Regulatory Affairs	IND Application	FDA overview of investigational new drug (IND) regulations
	FDA Meetings	Best practices document explaining communication between IND sponsors (drug companies) and the FDA
	Expedited Programs for Serious Conditions	FDA Guidance document explaining expedited programs for serious conditions (may or may not be applicable based on program)
	Drugs@FDA	Searchable compendium of approved drug products with up-to-date and historical labeling
Medical Affairs	Roles for Medical Affairs	Article explaining the role of medical affairs in moving from research and development to commercialization
Marketing/Commercial	Marketing for Pharmacists	Marketing slide-set prepared for IPhO
General Resources	Pharmacists Roles	IPhO published documents provide an overview of functional area roles

	IPhO Webinars	IPhO webinars presented by fellows and industry professional to elaborate on several topics relating to industry and drug development
Opioid Specific Resources	FDA Analgesic Drug Activities	FDA activities in analgesic drug development, research, and safety
	FDA Abuse-Deterrent Opioids Development	FDA presentation on the challenge of developing new pain medicines – developing novel analgesics and abuse-deterrent opioid formulations
	FDA Timeline of Opioid-related Activities	Timeline of FDA activities and significant events addressing opioid misuse and abuse
	FDA Guidance for Abuse-Deterrent Opioids	FDA Guidance for Industry – Evaluation and Labeling for Abuse-Deterrent Opioids

Tips Communicating with Your Fellow Chapter Partner

Each chapter will be paired with an industry fellow to serve as a chapter partner. Fellows who volunteer to partner with chapters typically have been involved with the VIP competition in past years, as a participant and/or chapter partner.

We strongly encourage that your chapter leverages your fellow chapter partner as a resource as a source of knowledge, experience, and advisement. In the past, chapters who have worked closely with their fellow partner have seen some of the best outcomes.

Tips to communication:

1. Make early introductions and maintain consistent contact. Each chapter will have their own needs, but, at-minimum, monthly communication is encouraged.

2. Set expectations and goals. Make sure your chapter partner is aware of the expectations and goals you've set for your ambitious project and what/when you will need more support. Fellows can be especially helpful with all aspects of your project.

3. Share best methods of contact (email, phone, Skype, etc…)

Tools for Creating your Final Presentation

Please follow this link to learn how to turn your presentation into a video.

Tips for good PowerPoint presentations.

Grading Rubrics

Please follow this link to view the final presentation submission grading rubric.