Value of Industry Pharmacists (VIP) Case Competition

(2020-21)

Competition Guide
Version 1.0

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 2020-21 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.

We also encourage participating chapters to seek advice from appropriate school faculty and chapter advisors that have industry experience.

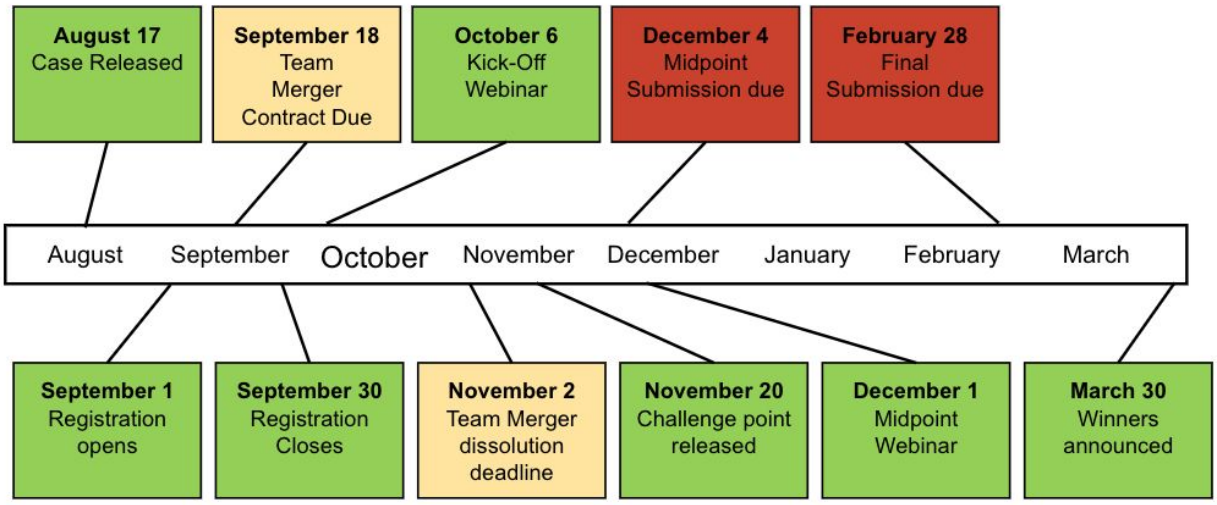
Purpose

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 submission deadlines. 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 1st - 30th**. Deliverables are indicated below in **red shading** Dates in yellow shading indicate the team merger timeline.



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 **December 4th, 2020 by 11:59 PM**. Please create a team google drive folder and email the folder link to the VIP case email. Create a PowerPoint submission of your team's presentation and submit it to **your 2020-21 VIP Case Google Drive** using the naming structure provided in the appendix.

Submissions received after the due date will be docked 4% of their overall competition score per week, not to exceed the 16% attributed to this section (as stated in the next section). Please submit a PowerPoint 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), including the Value of Industry Pharmacists. 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 16% of your chapter's final score. There are questions asked throughout the Competition Description section. The Midpoint Submission will be graded for completion. Functional area questions should be *thoughtfully answered*. Please see the Midpoint grading checklist, located in the appendix, for specific details. 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 28, 2021 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 **your 2020-21 VIP Case Google Drive** using the naming structure provided in the appendix. Video Submission length will be **limited to 45 minutes**. Submissions longer than 45 minutes will be penalized at a rate of a 1% deduction per minute over.

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.

Please record your presentation in PowerPoint and export it as a video. We are only accepting PowerPoint exported videos in order to compare videos across the same platforms. 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 create a robust go-to-market strategy that demonstrates your knowledge of 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 84% of the final competition score, with the midpoint evaluation comprising the other 16%.

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 March 2nd, 2020 at 11:59 PM EST will not be considered**.

The winning chapter will be selected by **March 30, 2021.**

The winning chapter will be recognized at the **2021 IPhO Annual National**

Meeting. The winning chapters will receive monetary awards as follows:

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

Midpoint and Final Submission Guidance

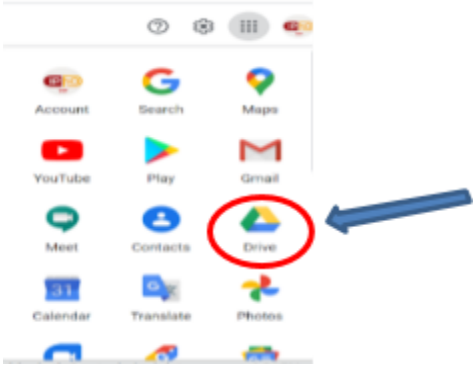
Midpoint and Final submissions must be submitted as PowerPoint presentations. The Final submission will also require a video of the presentation (please follow this link for video recording instructions). Tips for successful PowerPoint presentations may be found here, and the Final submission grading rubric may be found here.

Due to the large size of these submissions, we will be utilizing Google Drive for this year's Value of the Industry Pharmacist Case Competition (VIPCC). Please find the following steps to properly name, upload, and share both your Midpoint and Final submissions.

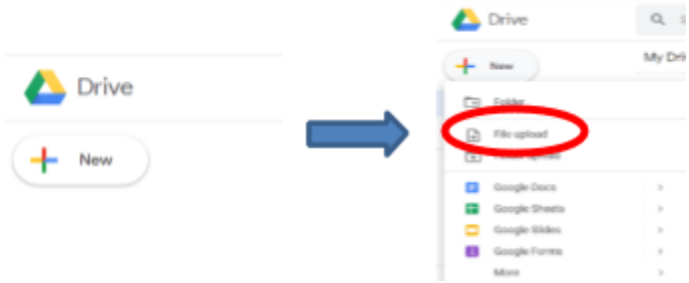
Uploading Submissions

Log into your school's IPhO Gmail account (or a personal Gmail account) and click the "dots" icon on the upper right corner of the screen:

Select the "Drive" option from the menu that appears:

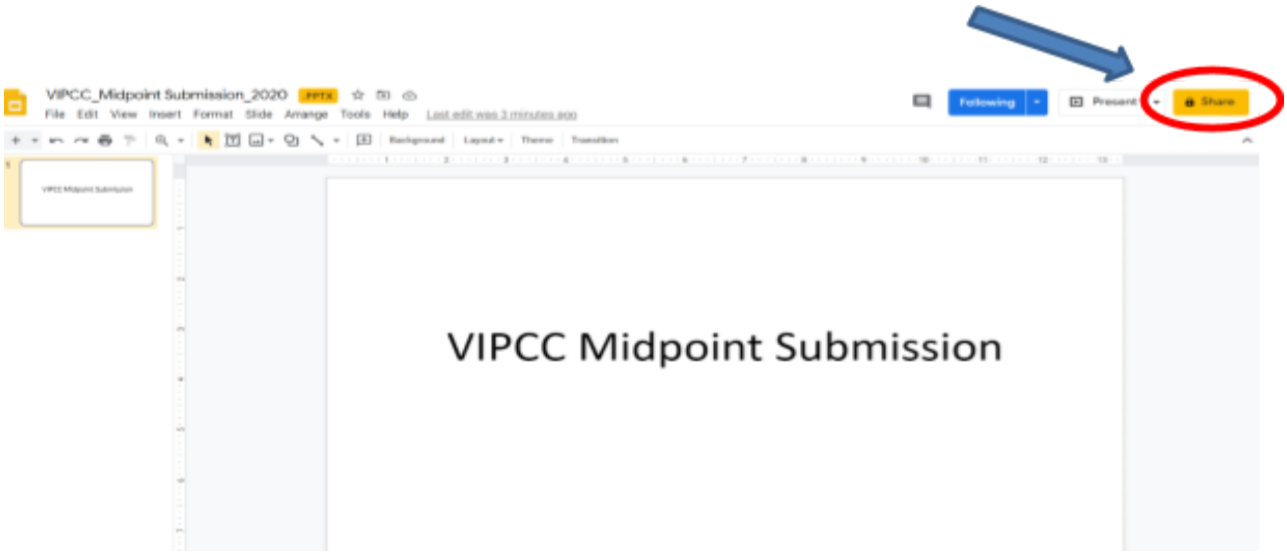


In the upper left of the Google Drive page, click the "+ New" button and then select the "File Upload" option to upload your submission PowerPoint:

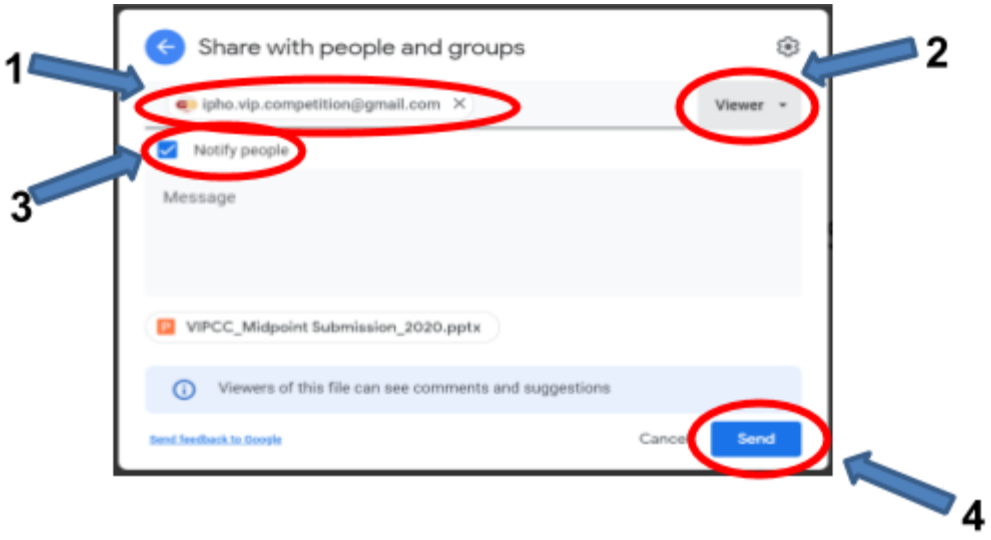


Sharing Submissions

Once the file has been uploaded, the PowerPoint will be converted to a “Google Slides” file. It is recommended to review the file to ensure that formatting and content was not altered during the upload process. Upon opening the presentation with Google Slides, you will have the option to share the presentation in the upper right:



Enter the VIPCC email in the field that appears (ipho.vip.competition@gmail.com) and assign viewer status. It is also very important to check the “Notify people” box. This will send a notification to the VIPCC leadership team upon sharing and will serve as a timestamp for the submission. Lastly hit “send”:



This process is the same for both the Midpoint and Final submissions.
If you have additional questions, you may reach out using the VIPCC email address.

2020-21 VIP Case Competition Description

Prologue

Eosinophilic asthma (EA) is a subtype of asthma that is often severe. In EA increased numbers of eosinophils are present in blood, lung tissue, and sputum, and these patients also frequently suffer from chronic sinus disease and nasal polyps[1]. EA occurs more frequently in patients who develop asthma as an adult, but also occurs in children and young adults. Childhood severe asthma is predominantly eosinophilic and almost a quarter of children with severe asthma have persistent airflow limitation.[2] The exact prevalence of EA remains debated, however about 10% of asthma cases are classified as severe refractory asthma[3]. Shortcomings in currently available treatments for EA is a critical issue. Recently, there have been targeted therapeutics approved by the FDA that focus on key cytokine inhibition in the eosinophil development pathway. Innovative formulations that include optimal pharmacokinetics, pharmacodynamics, and safety/efficacy outcomes are needed.

Case Profile

Your pharmaceutical company has recently discovered a new biologic entity (NBE), Actlizumab, an interleukin-5 (IL-5) antagonist humanized monoclonal antibody indicated for the treatment of severe asthma.

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 that would limit development in a pediatric population. In addition to asthma, clinical investigation of IL-5 antagonists have been seen in other eosinophilic conditions. 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 application (IND) with the FDA. However, there is still room for differentiation of this promising treatment. For example, it might confer a pharmacokinetic advantage of a less frequent dosing schedule or fewer drug-drug interactions.

Your company now wants to plan ahead and determine all of the appropriate activities and steps that are needed to establish a competitive formulation, gain regulatory approval and bring this NME to patients. **Your company has also determined that this molecule will have a pediatric indication at launch.** 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 maximally utilized in pharmaceutical drug development.

1 Nair P. What is an "eosinophilic phenotype" of asthma?. J Allergy Clin Immunol. 2013;132(1):81-3.

2 Fleming L, Heaney L. Severe Asthma-Perspectives From Adult and Pediatric Pulmonology. Front Pediatr. 2019;7:389

3 Walford HH, and Doherty TA. "Diagnosis and management of eosinophilic asthma: A U.S. perspective." Journal of Asthma and Allergy 7 (2014): 53-65.

Midpoint Submission

Key Functional Area Objectives and Questions

In the Midpoint Submission, as stated above, the bulleted questions included within each functional are required to be answered, and will guide your thinking and research in the development of your initial Powerpoint which should be used as your Midpoint Submission.

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 (RA)

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 BLA? (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 RA 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 a medication?
- 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 helps position them to be valued members within the 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 2 weeks prior to 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 2020-2021 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)

Additional resource for answers to common questions: The value of Industry Pharmacists (VIP) Case Competition Backgrounder

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. 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. **Two chapters that each have teams of less than ten members** have the option of combining their members to form one larger team. Teams that wish to combine can indicate to do so on the registration form at the beginning of the competition.

Q. Can I work with other people 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 the 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 upload all materials to **your VIP Case Google Drive** using the following title:

School Name VIP Case 2020-2021

Please title your submission materials (PowerPoints) with the following structure (based on the materials being submitted):

School Name_Midpoint Submission_2020

OR

School Name_Final Submission_2020

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, Compliance & Regulatory Information (Biologics)	Very helpful guide to help shape the clinical development plan for your monoclonal asthma drug program
	Clinical Research Overview	High-level overview of clinical research process to bring a new drug to market
	General pediatric information and study characteristics	Provides FDA guidance on safety, ethics, labeling, trial characteristics, and more
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)
	Biologics License Applications (BLA)	FDA overview of biologics license applications (BLA) regulations
	Drugs@FDA	Searchable compendium of approved drug products with up-to-date and historical labeling
	Pediatric Study Plans: Content of and Process for Submitting Initial Pediatric Study Plans and Amended Initial Pediatric Study Plans	This guidance provides the current thinking of the Food and Drug Administration (FDA) regarding implementation of the requirement for sponsors to submit an iPSP

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

EA resources	**Resource Name (With Link)**	**Resource Description**
Eosinophilic asthma and interleukin-5 (IL-5) antagonist	An algorithmic approach for the treatment of severe uncontrolled asthma	Introduction to anti IL-5 therapy in eosinophilic asthma
	Background on EA	American Partnership for Eosinophilic Disorders background on eosinophilic asthma (EU)
	Asthma treatment guidelines (2020)	Global Initiative for Asthma (2020) report that includes recommendations for the treatment of EU
	Pathophysiology of IL-5 in severe asthma	Describes the role of IL-5 in severe asthma and eosinophil development

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 midpoint submission grading checklist.

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