

Speaker/Moderator Guide

Learning Objectives

Upon completion of this program, participants will be able to:

1. Interpret data from emerging trials in the field of moderate-to-severe plaque psoriasis.
2. Identify the potential role of novel oral therapies in the Canadian plaque psoriasis treatment landscape.
3. Contrast the mechanism of action, route of administration, efficiency, and safety of different treatment options for moderate to severe plaque psoriasis.
4. Apply the latest clinical evidence to select a treatment plan that will result in significantly improved symptoms and to mitigate treatment side effects.

Scientific Planning Committee

Melinda Gooderham, MSc, MD, FRCPC

Kim Papp, MD, PhD, FRCPC

Accreditation

This event is an Accredited Group Learning Activity (Section 1) as defined by the Maintenance of Certification Program of the Royal College of Physicians and Surgeons of Canada, and approved by the Canadian Dermatology Association. You may claim a maximum of 1.0 hour (credits are automatically calculated).

Co-development: This program was co-developed by the Dermatology Association of Ontario and the International Centre for Professional Development in Health and Medicine, and was planned to achieve scientific integrity, objectivity and balance.

This program has received an unrestricted educational grant from Bristol Myers Squibb Canada.

Notes for Speakers/Moderators

- This program offers a selection of 17 short video presentations featuring expert Canadian dermatologists, who provide their answers to some of the most common questions from dermatologists about new and emerging novel oral therapies for the treatment of moderate to severe plaque psoriasis.
- The list of questions is provided in this guide, along with the duration of each video clip.
- Please be sure to include opportunities for engaging your local audience in discussions before and/or after presenting the video vignettes, in order to enhance the learning experience and to meet the RCPSC requirement for 25% interactivity for Section 1 credits. This will also help to provide the most valuable and practical take-home information for your attendees.
- Group discussion questions are included at the end of each of the four parts of the program:
 - Press the pause button (II) to allow time for discussion
 - Press the play button (▶) to restart the video
- You have been provided with a URL address to access the program to use in delivering your session.
- All session attendees will be asked to complete an evaluation of the program, which will provide feedback and guide future program development.

We wish you great success with your program!

If you have any feedback or questions, please contact info@icpdhm.com.

About the Program

This program features emerging data in the treatment of moderate-to-severe plaque psoriasis (PsO). In the introductory video, Canadian trialists Dr. Kim Papp and Dr. Melinda Gooderham explain the program and overarching concept. They will discuss a series of 17 rapid-fire questions on the current landscape of PsO treatment, and provide expert responses related to safe and effective treatments.

Expert Presenters



Melinda Gooderham, MSc, MD, FRCPC

Medical Director, SKiN Centre for Dermatology
Principal Investigator, Probit Medical Research
Assistant Professor, Department of Medicine, Queen's University
Consultant Physician, Peterborough Regional Health Centre
Peterborough, Ontario



Kim Papp, MD, PhD, FRCPC

Alliance Clinical Research
Founder and President, Probit Medical Research
Adjunct Professor of Medicine, Division of Dermatology, University of Toronto
Waterloo, Ontario

Program Questions

PART 1: Pathophysiology

01:07	1. What is the current treatment landscape of moderate-to-severe plaque psoriasis?
01:21	2. How do the mechanisms of these drugs differ?
00:60	3. Can you briefly describe the advances in targeted treatment?
01:16	4. What is the clinical evidence in terms of efficacy and safety of these therapies?

PART 2: Clinical Trial Program Findings in Oral Therapies for Moderate-to-Severe Psoriasis

01:12	5. Is there an unmet need for drugs with new mechanisms of action?
01:13	6. What is the status of deucravacitinib for approval in Canada?
01:28	7. What are the key findings from the POETYK trials?
01:26	8. What are the top-line takeaways of the trials?

PART 3: Canadian Clinical Impact of Clinical Trials

01:44	9. What are the clinical considerations for the use of novel therapies?
01:53	10. What is the potential clinical impact of oral therapies in moderate-to-severe plaque psoriasis?
00:60	11. How do these results impact the Canadian plaque psoriasis treatment landscape?
01:13	12. How are new clinical program results meaningful to patients?

PART 4: Trialists' Perspectives

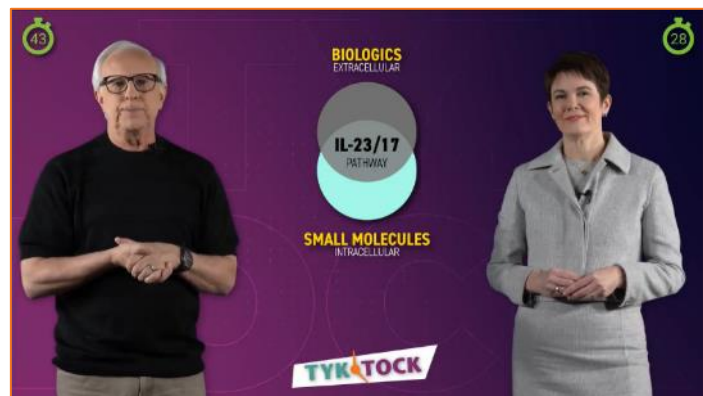
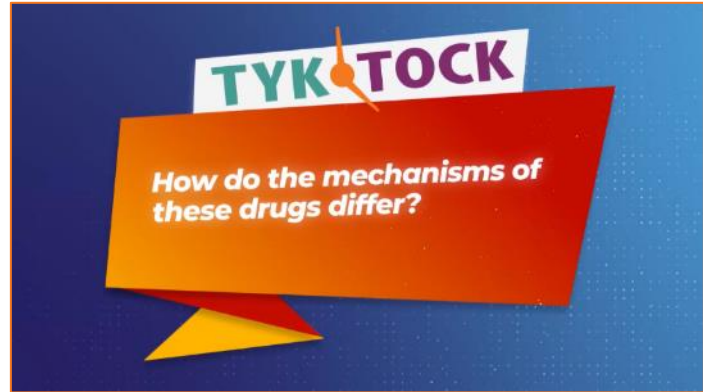
01:43	13. What is your perception of the real-world safety of upcoming new therapies?
01:13	14. As a primary investigator, what have you observed in your trial patients?
00:56	15. Based on your experience, which patients could benefit from upcoming novel treatments?
01:36	16. What has long-term data in the treatment of moderate to severe plaque psoriasis shown?
01:09	17. Can you highlight the importance of the POETYK trial results for both patients and HCPs?

Answer Highlights – Part 1: Pathophysiology

Question 1. What is the current treatment landscape of moderate-to-severe plaque psoriasis?



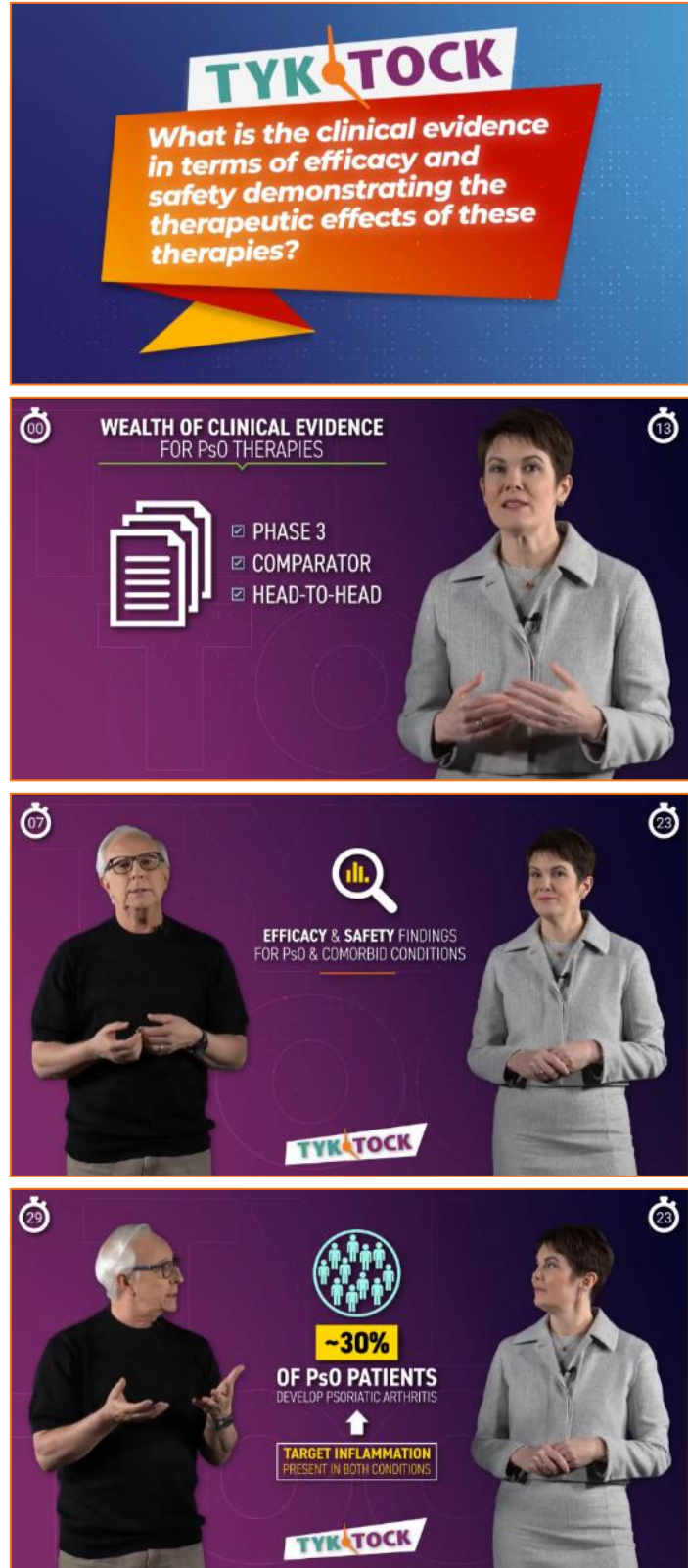
Question 2. How do the mechanisms of these drugs differ?



Question 3. Can you briefly describe the advances in targeted treatment?



Question 4. What is the clinical evidence in terms of efficacy and safety of these therapies?



TYKTOCK

What is the clinical evidence in terms of efficacy and safety demonstrating the therapeutic effects of these therapies?

WEALTH OF CLINICAL EVIDENCE FOR PsO THERAPIES

- ☑ PHASE 3
- ☑ COMPARATOR
- ☑ HEAD-TO-HEAD

EFFICACY & SAFETY FINDINGS FOR PsO & COMORBID CONDITIONS

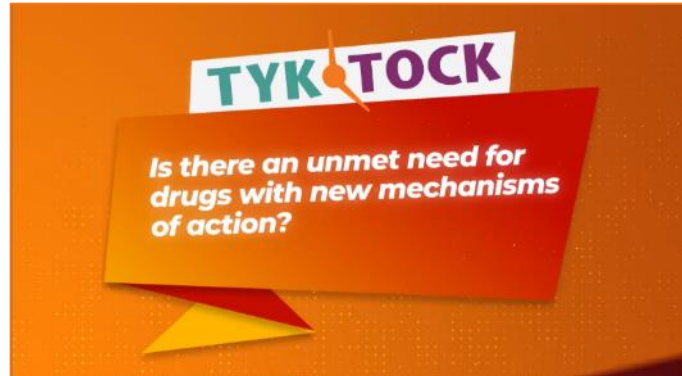
~30% OF PsO PATIENTS DEVELOP PSORIATIC ARTHRITIS

TARGET INFLAMMATION PRESENT IN BOTH CONDITIONS

TYKTOCK

Answer Highlights – Part 2: Clinical Trial Program Findings in Oral Therapies for Moderate-to-Severe Psoriasis

Question 5. Is there an unmet need for drugs with new mechanisms of action?



Question 6. What is the status of deucravacitinib for approval in Canada?

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What is the status of deucravacitinib for approval in Canada?

00 **20**

Health Canada

DEUCRAVACITINIB
→ MODERATE-TO-SEVERE PSORIASIS

POETYK PS0-1 & POETYK PS0-2

17 **30**

CLINICAL TRIAL DATA REFLECTED IN REAL-WORLD EXPERIENCE

24 **39**

DEUCRAVACITINIB
HIGHLY-TARGETED ORAL THERAPY
NOW AVAILABLE TO PATIENTS

TYKTOCK

Question 7. What are the key findings from the POETYK trials?



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PIVOTAL PHASE 3 POETYK PSO TRIALS
2:1:1 PATIENT RANDOMIZATION

DEUCRAVACITINIB 4 MG DAILY	PLACEBO	APREMILAST 30 MG TWICE DAILY
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00
27

WEEK 16 RESULTS

PASI 75 RESPONSE RATES

	POETYK PSO-1	POETYK PSO-2
DEUCRAVACITINIB	58.4%	53%
PLACEBO	12.7%	9.4%
APREMILAST	35.1%	39.8%

sPGA 0/1 RESPONSE RATES

	POETYK PSO-1	POETYK PSO-2
DEUCRAVACITINIB	53.6%	49.5%
PLACEBO	7.2%	8.6%
APREMILAST	32.1%	33.9%

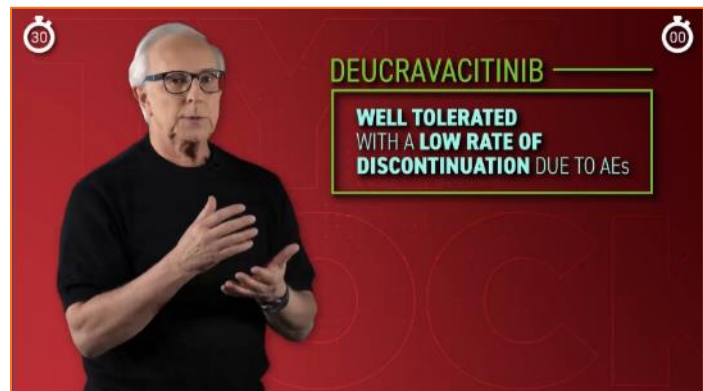
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53

WEEK 16 RESULTS

PASI 90 RESPONSE RATES

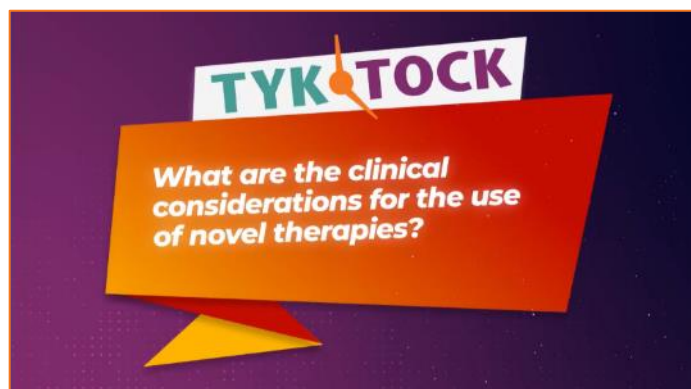
	POETYK PSO-1	POETYK PSO-2
DEUCRAVACITINIB	35.5%	27%
PLACEBO	4.2%	2.7%
APREMILAST	19.6%	18.1%

Question 8. What are the top-line takeaways of the trials?

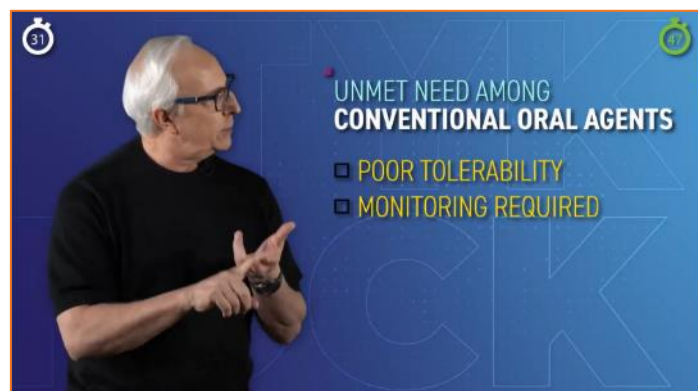
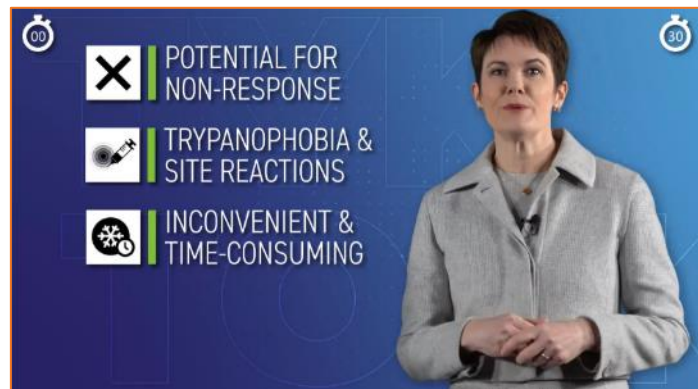


Answer Highlights – Part 3: Canadian Clinical Impact of Clinical Trials

Question 9. What are the clinical considerations for the use of novel therapies?



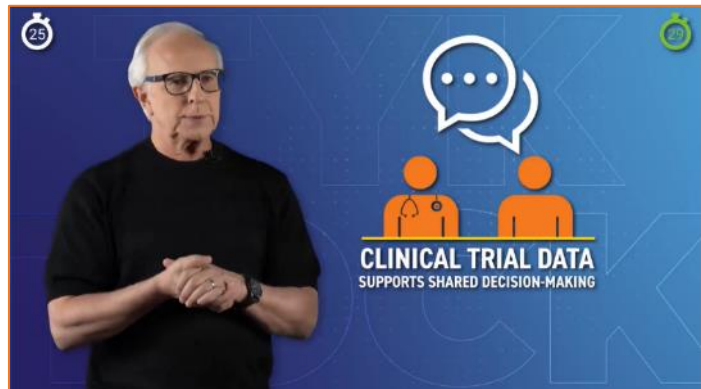
Question 10. What is the potential clinical impact of oral therapies in moderate-to-severe plaque psoriasis?



Question 11. How do these results impact the Canadian plaque psoriasis treatment landscape?

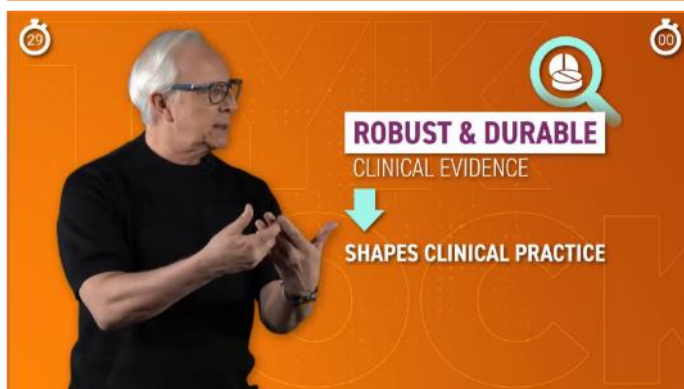


Question 12. How are new clinical program results meaningful to patients?



Answer Highlights – Part 4: Trialists' Perspectives

Question 13. What is your perception of the real-world safety of upcoming new therapies?



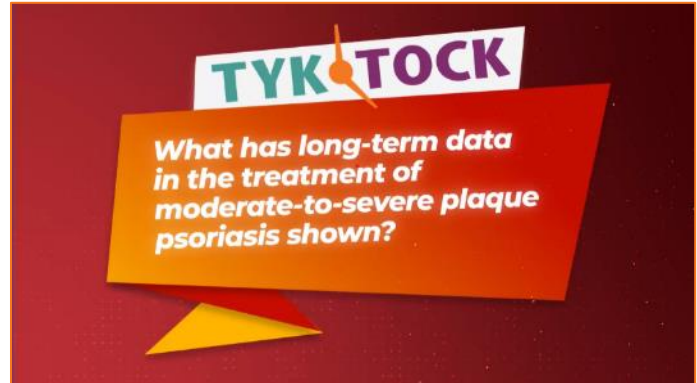
Question 14. As a primary investigator, what have you observed in your trial patients?



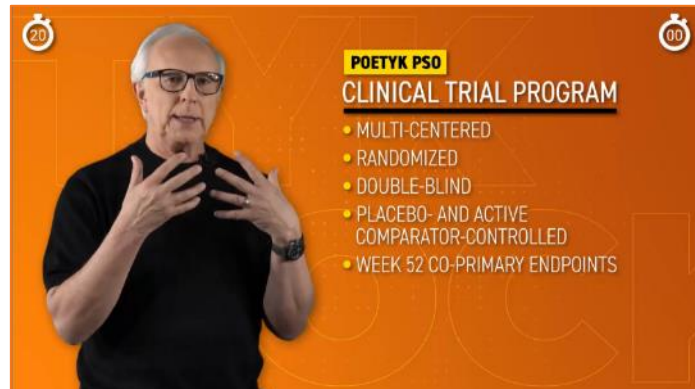
Question 15. Based on your experience, which patients could benefit from upcoming novel treatments?



Question 16. What has long-term data in the treatment of moderate to severe plaque psoriasis shown?



Question 17. Can you highlight the importance of the POETYK trial results for both patients and HCPs?



Discussion Questions

The following questions were developed to engage your local audience in discussions after presenting the video vignettes, in order to enhance the learning experience and to meet the RCPSC requirement for 25% interactivity for Section 1 credits.

PART 1: Pathophysiology

- What are your main takeaways from these data about TYK2 inhibitors for treatment of moderate to severe plaque psoriasis?
- How might TYK2 inhibitors meet unmet needs in the treatment armamentarium for moderate to severe plaque psoriasis?

PART 2: Clinical Trial Program Findings in Oral Therapies for Moderate-to-Severe Psoriasis

- What are the potential clinical implications of these efficacy and safety data in your treatment of moderate to severe plaque psoriasis?
- What are your main takeaways from these data?

PART 3: Canadian Clinical Impact of Clinical Trials

- How might these data affect your clinical decision-making for management of patients with moderate to severe plaque psoriasis?
- What are the potential benefits/implications on patient outcomes?
- How might novel oral therapies affect your management of patients with existing metabolic conditions such as diabetes?
- How might novel oral therapies affect your management of patients who have a pre-existing condition that suppresses the immune system?

PART 4: Trialists' Perspectives

- Of the data presented today, what do you feel might have the greatest impact on your current clinical practice?
- What other data are of interest to you regarding the efficacy and/or safety of TYK inhibitors for the treatment of moderate to severe plaque psoriasis?