



**BIKTARVY<sup>®</sup>**

bictegravir 50mg/emtricitabine 200mg/  
tenofovir alafenamide 25mg tablets

# BIKTARVY<sup>®</sup>

## Real Impact

# Interview Guide

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## Welcome, Dr. Gallant!

Thank you for spending the day with us. We're excited to record stories of your personal experience treating patients living with HIV, in addition to educational information related to HIV treatment considerations.

To help prepare you for the shoot, we've constructed this guide. It will provide an overview of your shoot day, highlight regulatory watch-outs we've received from PRC, and outline your interview.

# Overview



# Shoot Day 5/18/2021

During our time together, there are 3 types of content we will capture: B-roll, interview content, and scripted lines.

**B-roll:** Additional footage we'll shoot in the studio. It will feature you watching some archival footage as we capture your reaction to reminiscing about the last 40 years of the epidemic, in addition to some shots of the light from the footage reflecting off of you.

**Interview:** Here we'll revisit a lot of the topics we've already discussed with you over the last few months. The interview will be organized into 2 parts. First, we will focus on you and your story. Then, we will start to focus on disease state educational content. During this time, we may ask you to modify and repeat certain lines so they are compliant with PRC guidelines.

**Scripted Lines:** These are statements we have worked to create with PRC and will need to be captured verbatim. There will be a teleprompter, so don't worry about memorizing anything.

## Tuesday, May 18th (San Francisco—All Times PDT)

- 8:00am - 9am: Crew call-Breakfast, set up cameras, light, and HMU station.
- 8:30am: Agency & Client Call Time
- 8:30am: Talent-Doctor Joel Gallant arrives/Zoom link live
- 8:30am - 9:00am: Review wardrobe/HMU
- 9:00am: PRC call/wardrobe approval
- 9:00am - 12:00pm: Roll on interview with Dr. Joel Gallant
- 12:00pm - 12:30pm: Lunch
- 12:30pm - 1:30pm: Reset cameras, lighting, Wardrobe, HMU
- 1:30pm-4pm: B-Roll-Dr Joel Gallant in front of video archive wall/green screen
- 4pm - 4:30pm: Pick-ups/Thank You video
- 4:30pm: Wrap talent



# Watch-outs

- Avoid statements that imply comparatively better benefits. For example:
  - **Don't say:** "By 1995, we knew that better drugs were coming soon."
  - **Say:** "By 1995, we knew that new drugs with different mechanisms of inhibiting HIV were coming soon."
- Avoid the use of "we," which may be construed as meaning Gilead. Instead, speak for yourself as a member of the HCP community or about the field at large. For example:
  - **Don't say:** "What we have achieved over the past 40 years is amazing."
  - **Say:** "What the scientific and medical community has achieved/What I have witnessed over the past 40 years is amazing."
- When speaking about the present, be mindful not to imply that you currently practice medicine. For example:
  - **Don't say:** "Today, we know the power of starting treatment early."
  - **Do say:** "Today, DHHS guidelines recommend that patients should initiate HIV treatment immediately, if possible."
- Avoid talking about the clinical profile of BIKTARVY unless specifically asked. Disease state education cannot speak to or imply benefits of BIKTARVY.
- In the final video, viewers won't hear the questions you're being asked. It's important to rephrase the question so it provides needed context. For example, if you're asked "What's your favorite ice cream flavor?"
  - **Don't say:** "Vanilla ice cream."
  - **Say:** "My favorite flavor of ice cream is vanilla."

# It's all in the details

- Be open and honest. We want to hear your story. Authenticity is key.
- Make sure you're speaking in the first person.
- When sharing your unique story, use phrases like "I think" "I felt" or "For me" when describing your experience.
- Speak slowly and clearly. Take a pause in between sentences and thoughts.

# Some key words to avoid

- Confidence
- Control
- Power/Powerful
- Safer/Better
- Simplicity





# Interview Questions:

## PART 1

This section of the interview is about getting to know you, your personal journey as a clinician who treated patients with HIV, and why you came to Gilead. You can use the bulleted talking points as a reference for how to frame your answers, but feel free to speak from the heart during the shoot.

**1. Can you tell us about yourself, starting with your name and position at Gilead?**

My name is Joel Gallant and I'm an Executive Director of HIV Medical Affairs at Gilead.

**2. Tell us about your clinical training. How did you get started in HIV care and where have you practiced?**

I was a medical student in San Francisco in the early 1980s.

I probably cared for my first patient with AIDS in 1983.

HIV has been the exclusive focus of my career since 1990. I spent most of my time at Johns Hopkins Hospital in Baltimore. Later, I ran a community-based HIV clinic in Santa Fe. I also did yearly teaching rotations in Uganda.

I came to Gilead in 2017.

**3. How does it feel to look back on the last 40 years of the epidemic?**

Looking back over the last 40 years, it's incredible how far we've come and how fast. It sure didn't feel fast at the time.

**4. What advice would you give your younger self?**

If I were able to give advice to my younger self, I'd say, "Prepare yourself for a long, painful fight, but one day you'll feel hopeful again. You'll see tremendous progress over the course of your career, and you'll be gratified if you ever retire."

**5. Why choose to jump into the field of HIV medicine at the height of the epidemic?**

Free form response

**6. How would you describe the early days of the epidemic? What did you experience as a clinician?**

The early years of the AIDS epidemic were a nightmare.

Those at risk, if they weren't already sick, were terrified of becoming sick and dying.

There was no test and the only treatments we had were for opportunistic infections or malignancies that occurred at late stages of the disease.

There was horrendous stigma, even within the medical profession.

**7. How did it feel once drugs started to become available in the late 1980s?**

Drugs started to trickle in starting in the late 1980s, but their effects were short-lived.

We later learned that drug-resistant strains of HIV were rapidly emerging, even though we couldn't measure it clinically back then.

HIV drug resistance became a huge challenge for the field, and remains a challenge today.

# Interview Questions



**8. When did you start getting the first glimmers of hope that the tide was turning against HIV?**

By 1995, we knew that new drugs with different mechanisms of inhibiting the virus were coming soon.

It was really the Vancouver AIDS Conference in the summer of 1996 that was the turning point.

After that conference, there was something different we could do for our patients.

Now we could attack the virus with a combination of drugs that used more than one mechanism of action.

Rather than just reducing viral load, which we could now measure, it was possible to suppress it durably.

Durable viral suppression inhibits replication and the chance for mutation.

**9. Is there a patient you will always remember who didn't make it to see the advent of HAART? Why is that the person that comes to mind?**

Free form response

**10. Do you remember your very first patient whose viral load came back undetectable? How did that make you feel? What was their reaction when you told them? Why do you think it was so impactful for you?**

Free form response

**11. What's the biggest difference between when you started treating patients and now?**

When I started treating patients, the average survival time of a patient diagnosed with HIV was maybe months to a few years because we had no treatment at all. By the time I left clinical practice in 2017, most of my patients were in their 50s, 60s, or 70s. I fully expected them to live a long life and die of something other than HIV.

My conversations with my patients weren't focused just on antiretrovirals or resistance anymore, but about primary care issues and healthy aging. We always monitored their HIV, but with their current therapies, HIV was not the top concern in many cases.

We've come so far in 40 years, and remembering what we've learned about resistance is one key component in the fight to end the HIV epidemic.

# Interview Questions





# Interview Questions:

## PART 2

In this section, we will discuss more about the disease state insights pertinent to your video. During the shoot, we will capture both the bulleted statements, as well as your authentic response. Remember to be you and refer back to page 5 for any guidance.

### **1. Was HAART all good news? What challenges remained?**

The era of HAART wasn't all good news. The few regimens we had were toxic, complicated to take, and prone to resistance emerging.

Many patients already had extensive resistance to the earlier drugs that they'd been taking as mono- or dual-therapy.

So when new drugs would come along, it wasn't always possible to put fully active combinations together, which made resistance to the new drugs almost inevitable.

### **2. Were the worst cases of resistance you saw caused by non-adherence to therapy?**

We often think of resistance as the result of non-adherence, but some of the worst resistance I dealt with was in patients who had done everything we told them to do back in the early days of the epidemic.

### **3. What did clinicians treating HIV have to know about resistance back in the first half of the epidemic?**

Being a clinician treating HIV back in the '80s and '90s meant knowing resistance inside and out.

Most of our case discussions at Hopkins involved presenting patients' treatment histories along with their accumulated resistance mutations. Then we would try to piece together regimens that would work in spite of those mutations. Those regimens were usually very complex.

### **4. What changed to make resistance something that wasn't thought about as often?**

As medicines advanced over time and with higher genetic barriers to resistance, we didn't have to worry about the development of resistance as often.

### **5. How did emerging prescribers learn about resistance?**

Newer providers were less familiar with concepts that had been common knowledge just a few years earlier.

When I was teaching, I used to say to my trainees, "Let me tell you what it was like when you had to think about resistance with every single patient."

### **6. How did you approach discussing resistance considerations with patients who were virologically suppressed?**

In patients who were virologically suppressed and doing well on treatment, we would talk about the mutations they had developed in the past, and whether their current regimen was the best one for their resistance profile.

### **7. Is resistance still a threat to patients today?**

It's great for patients that resistance is no longer the threat it once was, but it's still a threat. Resistance can still occur.

# Interview Questions



Resistance considerations are still highly relevant to the treatment choices clinicians make, and clinicians need to be prepared to deal with resistance if it emerges.

#### **8. What are the goals of HIV treatment? Have they changed since 1996?**

In many ways, the goal of HIV treatment hasn't changed since 1996.

The overriding goal is always viral suppression, because none of the other benefits of therapy are possible without that.

All regimens should do a great job at viral suppression. That's important both for the patient's health, and from a public health standpoint.

#### **9. Can you tell us what you mean about viral suppression being important for public health?**

According to DHHS, when your patients achieve and maintain an undetectable viral load for at least 6 months, it prevents sexual transmission of HIV to their partners.

We know that treatment is prevention. Undetectable equals untransmittable. U=U. As a public health principle, this means treaters can reduce the overall number of HIV cases by bringing down the viral load in their communities.

#### **10. Should viral suppression be the only consideration when selecting a therapy?**

Viral suppression should never be the only consideration. You have to think about the barrier to resistance, tolerability, long-term toxicity, and simplification of dosing.

The resistance barrier is especially important to ensure a durable virologic response. We want to minimize the possibility of new resistance developing.

#### **11. How do you think about resistance? How would you define it?**

I always say resistance is a permanent, irreversible toxicity (adverse event). Once you have resistance mutations, they're archived in your latent reservoir forever.

We should treat people with regimens that minimize the potential for this toxicity (adverse event).

#### **12. What advice do you have for clinicians considering simplification of therapy for their patients?**

Simplification of therapy—by reducing the number of pills, drugs, or doses—is a popular thing to do. It's often readily achievable, but we can't do it carelessly.

#### **13. What did we observe about switching from a high-barrier regimen to a lower-barrier regimen in the SWITCHMRK study?**

As we saw in the SWITCHMRK study, switching from a high-barrier regimen to a lower-barrier regimen can lead to virologic failure, especially in patients with a history of failure on older regimens. The changes we make should always be guided by a knowledge of the patient's treatment history, including both documented and presumed drug resistance.

#### **14. Do you recall any patients you treated with highly resistant virus who did not benefit from**

# Interview Questions



### **simplification of therapy?**

Free form response

#### **15. What do you want clinicians who practiced in the early HAART era to pass on to new prescribers?**

I want to make sure that those of us who practiced in the early HAART era pass on what we learned about resistance to new prescribers.

Background resistance can be present even in fully suppressed patients. It can emerge with suboptimal therapy or adherence.

I would never want to go back to the way things were, when we lived and breathed resistance.

# Interview Questions





# Additional Questions

If we have time to cover these questions, we will. These will range from more personal questions to other disease state education topics.

### **Disease Education**

1. How do you convey the urgency of staying ahead of the virus when resistance is much less common than before?
2. How important is it to initiate treatment immediately? What are the risk of delaying treatment?
3. Did you encounter any patients who wanted to delay starting treatment immediately? Why do you think patients would want to delay treatment? What are strategies you used to overcome these barriers?
4. What were some of the key needs of PLWH over 50 in your clinical experience?

### **Branded**

1. How would you explain to an emerging treater what undetectable means to and enables for a patient? What does U=U mean in your own words?
2. What aspects of the BIKTARVY clinical data offer a clinician “Durability you can trust”?
3. If you had to summarize the BIKTARVY efficacy story in 2 or 3 sentences, what would you say?
4. What would you say to healthcare providers about the Week 192 long-term safety of BIKTARVY?

### **Aspirational**

1. Clinicians have a lot of great options when it comes to treating HIV. What standards of care do they need to evaluate their regimen choices up against when deciding on treatment?
2. What makes you the proudest to be part of the community of HIV treaters? Why?
3. Who do we have to thank for the medical advancements that have brought us so far in the last 40 years?
4. What would you say to emerging clinicians treating HIV about the legacy they are joining? What is your hope for where they can take the field?

### **Personal**

1. What area of HIV medicine interested you the most? Why?
2. Given how dark things got by the height of the epidemice, why didn't you give up and switch to a different field of medicine?
3. Has studying HIV and living through the epidemic for nearly 40 years changed your perspective on life? Why do you think it has?
4. In what ways was your experience living through the epidemic different from your experience treating through the epidemic?

# Additional Questions





# Scripted Lines

These lines are important to capture and should be read exactly as shown.  
Don't worry about memorizing them—we'll have a teleprompter.

- Learn if BIKTARVY is right for your patients.
- Learn more about initiating treatment early with your patients.
- Consider a regimen's resistance barrier when choosing a treatment.
- BIKTARVY offers you durability you can trust.
- BIKTARVY offers a simple start for providers and patients.
- A treatment with a high barrier to resistance is key.
- HIV is one of the fastest mutating pathogens and can mutate millions of times per day.
- Mutations can affect ARV target proteins, resulting in potential drug resistance.
- Drug-resistant mutations may develop depending on a regimen's resistance barrier and during periods when drug levels are suboptimal.
- Resistance, HBV, CD4, and viral load testing should be performed at treatment initiation.
- However, you do not have to wait for the results before starting patients on BIKTARVY.
- Once test results are received, evaluate the appropriateness of continuing treatment.
- BIKTARVY is not indicated for patients with resistance to any component of BIKTARVY.
- BIKTARVY is not recommended in patients with severe renal impairment or severe hepatic impairment.
- BIKTARVY is contraindicated with two medications—dofetilide and rifampin.
- When considering a regimen change, it's important to consider all its attributes and whether it is the right fit for your patient.
- The most common adverse reactions in clinical studies through week 144 were diarrhea, nausea, and headache.

# Scripted Lines

