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**Introductions**

**Mr. Brooks Introduction:** "Hello, my name is Ron Brooks and I am the Managing Partner for Strategic Business Innovations. I have over 25 years of consulting experience but the last eight years have been heavily focused in the Life Sciences/Medical Industry. I've executed over 50 full scale primary research projects involving interviews and supporting focus groups. I'll be your lead moderator for this session.

**Ms. Fatheree Introduction:** "Hello, my name is Lisa Fatheree and I am the Director for the College of American Pathologists (CAP) Pathology and Laboratory Quality Center. We're the division responsible for developing evidence-based guidelines and are separate from the Laboratory Accreditation Program (LAP). On behalf of the CAP, thank you for participating in this focus group on "Improving the Impact of Laboratory Practice Guidelines: A New Paradigm for Metrics", a cooperative agreement project funded by CDC. We look forward to learning about your experiences with the immunohistochemistry validation guideline in your laboratory and exploring your suggestions for improvement including tools and resources. During the meeting I will assist in taking notes; however, we are not recording or taping this session and your individual responses will remain anonymous in an aggregated report.

**Ms. Souers Introduction:** "Hello, my name is Rhona Souers and I am a Senior Biostatistician for the College of American Pathologists. I have worked for more than 20 years at the CAP on projects ranging from quality improvement studies to instrumentation validation tool development. Currently, I am the lead statistician for this project and I've previously worked on the development and analysis of the IHC baseline practice characteristics survey. I will also assist with note-taking during this session."

**Dr. Fitzgibbons Introduction:** Hello, I'm Dr. Patrick Fitzgibbons and I served as the Chair and lead author for the IHC Validation guideline. I work at St. Jude Medical Hospital and I'm here to help answer any questions you might have.

**Dr. Astles Introduction:** Hello, I am Dr. Astles and I am here on behalf of the Centers for Disease Control and Prevention Division of Laboratory Systems, which is sponsoring this focus group under a cooperative agreement project with the College of American Pathologists.

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**Mr. Brooks:** “Now that you all know who we are, please introduce yourselves by providing your name, institution with city and state, and current position and experience in the laboratory. The CAP and CDC conducted a post-survey in 2015 and telephone interview on the immunohistochemistry validation guideline earlier this year. For this focus group, we’ll cover topics including awareness, adoption and your laboratory’s implementation successes and challenges. We’ll have a specific focus on opportunities for the future. We are going to be talking about both initial validation and revalidation recommendations so feel free to interchange but specify when describing your experience. Our questions are intended to be open-ended and can be answered with positive, negative or neutral responses. Please feel free to refer to any handouts (Attachment G) throughout the session. There are no right or wrong answers and no repercussions. Does anyone have any general questions about this focus group before we begin?”

*Mr. Brooks proceeds to begin asking questions.*



### Phase 1: Awareness/Adoption

1. How many here are very familiar with the guideline?
  - a. How did you hear about it?
  - b. What's your preferred method for being notified about guidelines?
2. How many here have adopted all or some of the recommendations?
  - Thanks for your response. We'll explore your reasons for adoption or non-adoption of the specific recommendations throughout the session.
3. Did anyone have disagreements with some of the specific recommendations?
  - Probe: Can you describe which recommendations and reasons for disagreement?

### Phase 2: Implementation Successes and Challenges

1. Which recommendation(s) was/were easiest to implement?
  - Probes: Why was it/what made it easy to implement? ... Which recommendations apply most to your laboratory?
2. Which recommendation was most challenging to implement?
  - Probe: Why was it/what made it difficult to implement?
3. How did institutional (organizational) support or resistance affect the timing of adopting recommendations into your laboratory?
  - Probes: Could you elaborate on some of the ways your institution provided laboratory support? ... Could you provide some examples of resistance observed in your organization?

### Phase 3: Opportunities for Improving Usefulness of CAP Guidelines

1. Were you aware of the toolkit available on the CAP guideline website?  
(Ms. Fatheree demonstrates the webpage [http://www.cap.org/web/home/resources/cap-guidelines/current-cap-guidelines/principles-analytic-validation-immunohistochemical-assays?\\_afLoop=1030220231883818#%40%3F\\_afLoop%3D1030220231883818%26\\_adf.ctrl-state%3D118xpd3bvy\\_4](http://www.cap.org/web/home/resources/cap-guidelines/current-cap-guidelines/principles-analytic-validation-immunohistochemical-assays?_afLoop=1030220231883818#%40%3F_afLoop%3D1030220231883818%26_adf.ctrl-state%3D118xpd3bvy_4) and tools via laptop projector and Mr. Brooks explores each resource)
  - a. The Summary of Recommendations
  - b. The PowerPoint presentation describing the guideline methodology and recommendations
  - c. The FAQs listing common queries
  - d. The Methodology Supplement
  - e. Review article by Drs. Goldsmith, Fitzgibbons and Swanson
2. What did you find useful/not useful about the toolkit documents?
  - Probes: What resources from the toolkit do you or your laboratory reference most? ... How has the toolkit benefitted your individual/laboratory practice? ... How can it be improved?... What would you like CAP to change or expand on etc. for the future revision?
3. Do you think a template would have been helpful to implement the guideline?
  - Probes: In what circumstances would a template be most helpful for the validation procedures? ...Would it be the same for revalidation procedures?... How would these templates aid in your laboratory work?



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4. What else would be useful in the future to help with the implementation of this guideline in your laboratory?
  - Probes: Could anyone share an idea for making the implementation process easier, for example, by sharing rare specimens between institutions?... Is there anyone in your laboratory we could speak with to help with the implementation process?
5. What other tools/approaches for future guidelines in general would be useful to your laboratory? (Disclaimer that all ideas will be shared for future developments but cannot guarantee)

**Closure:**

**Mr. Brooks:** "Your participation was valuable to both the CAP and the CDC. We will publish the final outcome as part of the cooperative agreement and all individual and laboratory information collected during this focus group will remain anonymous and summarized in aggregate in a future publication. We can provide a draft copy of this focus group report for your review if requested. In addition, your specific input will be shared with the CAP expert panel as they review the literature from 2014 onward in the potential revision and update of the "Principles of Analytic Validation of Immunohistochemical Assays" guideline, scheduled to commence in 2018. Your feedback from today is appreciated and matters to our next steps. Thank you for joining us today and enjoy the rest of your meeting!"