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## Dear Plcc Alliance

Join us this afternoon for our monthly updates meeting

**Wednesday, April 27, 2022 at 3:00-4:00 PM Eastern Time.**

This is an online meeting open to all Plcc members. Please find the meeting credentials and agenda below.

### Add event to calendar



[Link to Meeting Credentials](#)

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## Agenda (download [.docx](#)):

### Updates

- CLIAC meeting
  - API Public Comment April 2022

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- Keith Kaplan presented “Digital Pathology: The Past, Present, and Future”
- Decision summary PAIGE prostate
  - Plcc and Paige regulatory team engaged in the planning process. Look out for time and announcement
- Grand challenges discussion session took place on 4/25
  - Touched upon key elements from a regulatory submission
- AACR New Orleans – brief review
- Reminder: CLIA-C waiver project – if interested please e-mail
- Microsoft Teams channel established
  - Direct file exchange with FDA enabled (major accomplishment)
  - GANTT chart web-design CALL FOR HELP
    - Does anyone have web-dev skills to assist us?

### **Patient advocacy**

- FOCCR 2021 annual report
- APPIA protocol development (next meeting pending; interest => email join)
- Sepsis alliance (follow-up meeting)

### **EMA corner = “outside the box”**

- ICH guideline Q14: Intended for analytical procedure development
  - ICH Harmonization for better Health EMA

### **FDA**

- New guidance for certain products between “drug” and “device”
  - Example: Ophthalmic Products

### **Papers**

- Nirmal et al., The spatial landscape of immunoediting in primary melanoma at single cell resolution
- Bhate et al., Tissue schematics map the specialization of immune tissue motifs and their appropriation by tumors
  - Setty. Tissue Schematics: A framework to decipher tissue architecture and assembly
- Vasudevan et al., Digital biomarkers: Convergence of digital health technologies and biomarkers

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## Resources

- HAL: Nicolas Rougier, Scientific Visualization
- Python ML
- Report 2022: Clinician of the Future
- Bruce Quinn 2022: Cancer Patient and Access to Molecular Diagnostics

## News and Events

- **May 9-12** API Summit Pittsburgh; Plcc events **5/10** and **5/11** at a TBD location
- **June 3-7** ASCO meeting Chicago; Question => joint (formal) event?
- **June 6 at 10-11 AM ET** PathML: an open-source software toolkit for computational pathology research ([link](#))

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Looking forward to seeing you all there. Please reach out with any questions or comments.

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