

Global Regulatory Strategic Planning Group

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Goals

We believe that by renewing and expanding our collaboration with the US FDA, and forging collaborations with other regulatory agencies, BloodPAC will be able to share our collective experiences with these regulatory bodies and ultimately provide efficiencies in the approval process to bring liquid biopsy testing to more patients worldwide

- BloodPAC will seek deeper engagement with the US FDA to accelerate appropriate utilization of liquid biopsy testing within the United States
- BloodPAC will bring together other organizations world-wide that share our goal of improving patient outcomes with blood-based cancer diagnostics
- BloodPAC will collaborate with regulatory agencies world-wide to attempt to harmonize expectations of liquid biopsy test performance and appropriate clinical implementation

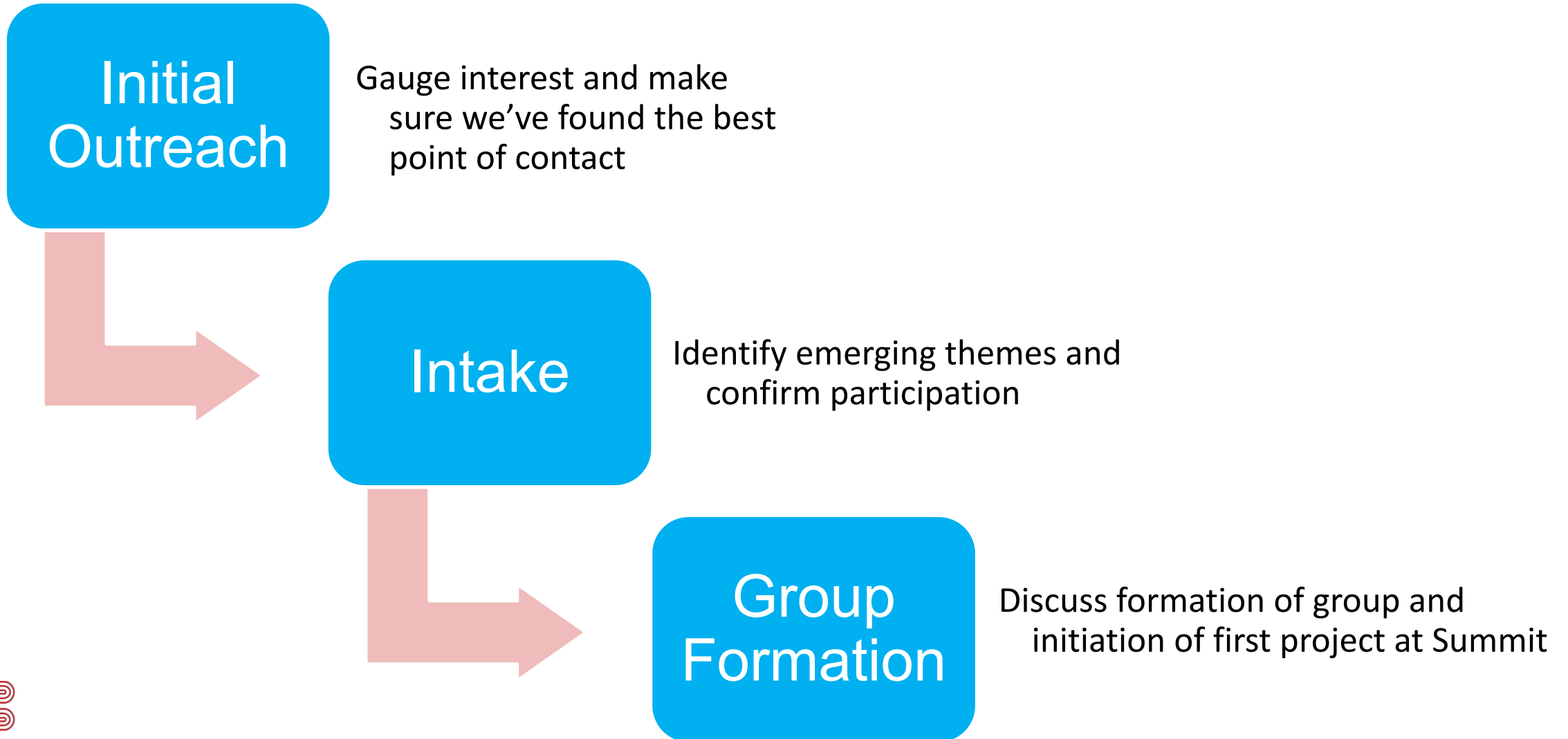


Agenda

- Progress Update
- Summit Plan
- Brainstorming Session for Fireside Chat



Regulatory Agency Group Formation



Intake Completed

- Canada: Health Canada (HC)
- Japan: Pharmaceuticals and Medical Devices Agency (PMDA)
- Israel: Ministry of Health (MoH)
- US FDA (CDRH – Reena Philip and Soma Ghosh)

- Seeking **1** additional member prior to the Summit!

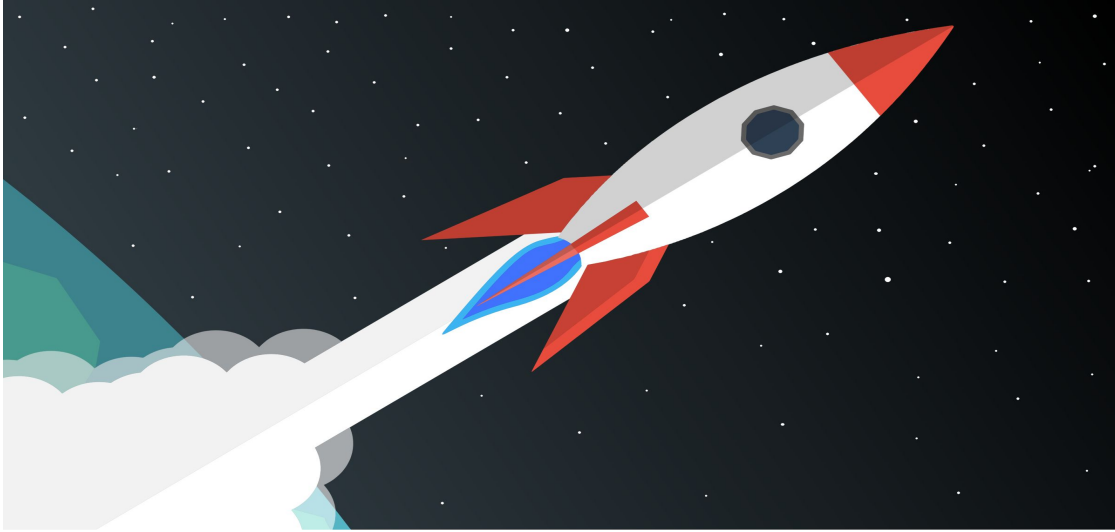


Group Formation

- Planning a mid-March initial meeting of the group (Goal: 5 Regulatory Agencies represented)
- Discuss emerging themes from intake (Challenges/Opportunities/MRD)
- Identify and discuss what potential projects could help accelerate regulatory approvals globally for liquid biopsy technologies
- Prepare for project launch at Summit



Summit Plans



Launch of Global Regulatory Strategy Group Project:

Hakan Sakul (BLOODPAC Team Leader)

Global Regulatory Agencies in Attendance



Goals of Launch:

- Discuss common challenges across global community
- Discuss first opportunities for global collaboration
- Identify an initial project that would benefit global harmonization of liquid biopsy regulatory approval

Summit Plans



Fireside Chat with the FDA:

Julia Beaver (CDER)

Reena Philip (CDRH)

Elaine Katrivanos (BLOODPAC moderator)



Goals of Fireside Chat:

- Value of BLOODPAC to FDA
- Value of Global Harmonization to FDA
- Value of Liquid Biopsy to Center for Drugs
- Future Directions – MRD and Clinical Trials

Value of BLOODPAC to FDA (Proposed)

- What grade would FDA give BLOODPAC for its work over last 5 years?
- What impact has BLOODPAC's work had on applications you've seen?
- What are some of the biggest challenges and opportunities that you think BLOODPAC can help with?
- How can we make FDA feedback to BLOODPAC more available?



Value of Global Harmonization to FDA (Proposed)

- What benefits do you see in aligning liquid biopsy clinical expectations globally?
- What challenges do you anticipate in liquid biopsy expectation global alignment?
- Do you think advanced science at FDA is similar to other global regulatory agencies?
- Is “First in the world” still a goal at CDRH?



Value of Liquid Biopsy to Center for Drugs (Proposed)

- How has liquid biopsy diagnostic testing influenced therapeutic product development?
- What opportunities/challenges does liquid biopsy still present in therapeutic space?
- How might liquid biopsy help increase access to precision medicine?
- What unmet medical needs could liquid biopsy testing help address?

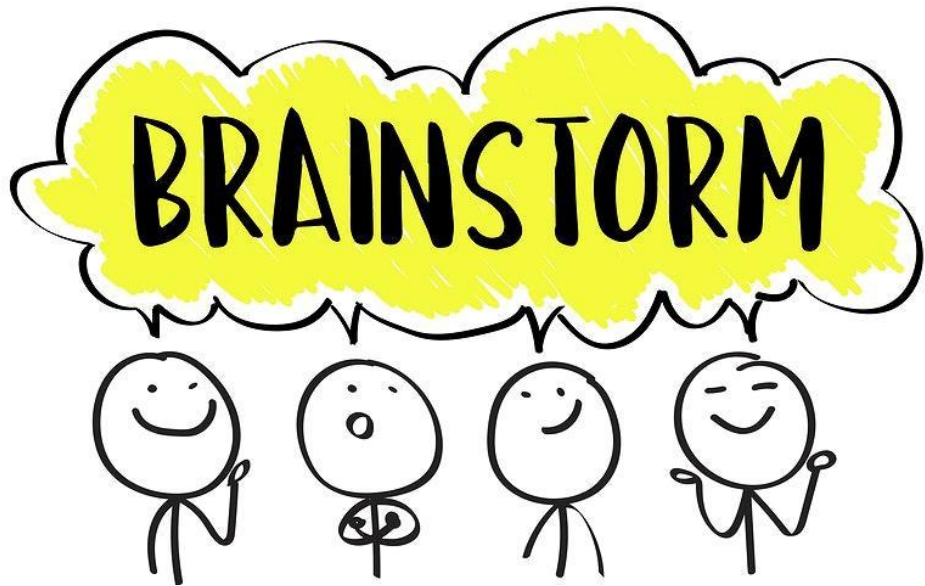


Future Directions – MRD and Clinical Trials (Proposed)

- What will it take for FDA to approve a precision therapeutic with liquid biopsy testing only?
- MRD testing with no presurgical plasma baseline in clinical trials?
- What are the global implications for liquid biopsy-only testing?
- What expectations do you have for liquid biopsies in clinical trials?
- Do you see liquid biopsies as potentially practice changing?



What are YOUR Burning Questions?



Goals of Fireside Chat:

- Value of BLOODPAC to FDA
- Value of Global Harmonization to FDA
- Value of Liquid Biopsy to Center for Drugs
- Future Directions – MRD and Clinical Trials



BLOODPAC

Thank you!

