



US IUO BioFire® BJI Panel Basic Product Knowledge and MEP Process Training

October 28, 2020



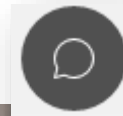
Presenter:

Jenn Baird, PharmD
Global Product Manager
Email: Jennifer.baird@biofiredx.com
Call/Text: +1 (385) 280- 9547



Host:

Cynthia Levinthal
Scientific Content Specialist





BJI MEP Kick-off: Product and Process Webinar

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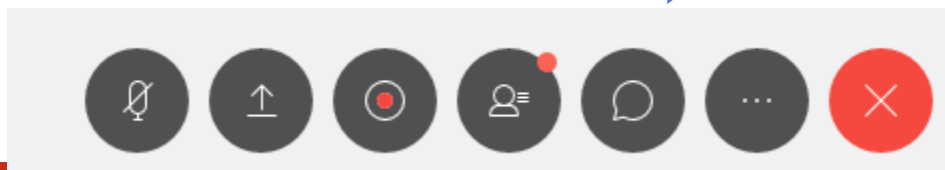
The Webinar will begin shortly

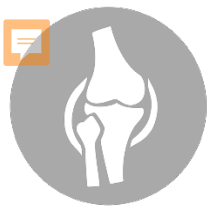
- We are all currently muted
 - Please also mute yourselves!
- Use the chat box to ask questions (click the chat icon to open chat box)
- Chat to Cynthia privately or to everyone
- There will be a prize for best chatter!
- We will open phone lines at end

Q&A Panel to follow

- Jennifer Baird, answerer
- Cynthia Levinthal, questioner

Click icon on your screen to chat!





Agenda

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1. **Bone and Joint Infections and Market Overview** – 5 mins
2. **The BioFire® Bone and Joint Infections Panel** – 15 mins
3. **Marketing Evaluation Program (MEP) Kickoff** – 15 mins
 1. Target accounts
 2. Contracting
 3. Site set-up and delivery
 4. Collateral
 5. Survey Process
 6. Product Launch and Wrap up
4. **Questions** -15 mins

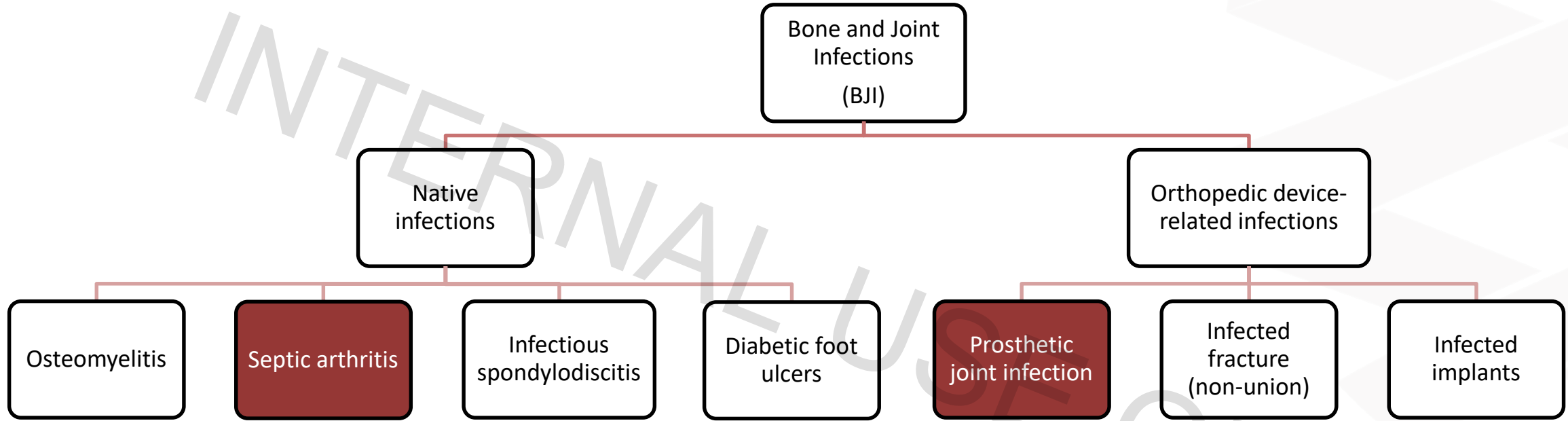




BJI: A Broad Spectrum of Diseases

Our Focus: Septic Arthritis and Prosthetic Joint Infections

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Septic Arthritis Market

~71,000 total diagnoses in U.S. in 2014¹
~200,245 SA Claims in 2018²

Prosthetic Joint Infection Market

~195,000 total diagnoses in U.S. in 2014¹
~419,265 PJI Claims in 2018²

Other infection types less suitable due to sample type (e.g., swab, tissue, bone) or pathogen menu

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2. Definitive Healthcare 2018 Total Estimated All-Payor Institutional Claims

3. Uptodate



Unmet Clinical Need

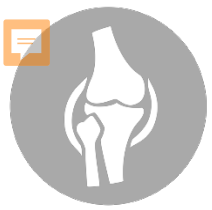
Prosthetic Joint Infections

- 195,000 diagnoses annually¹
- \$1.6 billion to treat by 2020²
- Diagnosis of PJI remains a challenge and no **gold standard test exists**⁵
 - Culture results can take up to 2 weeks
 - Poor recovery rates of Fastidious /Anaerobic/Bio-film organisms
 - Culture-negative PJI occurs in up to 35% of infections⁴
- When missed or undertreated, PJI leads to:
 - **unnecessary multiple surgical revisions** causing poor function or disability, considerably impairing quality of life⁶
 - **inappropriate treatments involving** prolonged use of IV antibiotics⁷

Septic Arthritis

- 13,714 hospitalizations in 2012³
- \$759 million in hospital charges³
- Acute monoarticular arthritis in adults presenting to the ED has **multiple potential etiologies** including infection (bacterial, fungal, mycobacterial, viral), crystalloid arthropathies, rheumatoid arthritis, lupus, and trauma⁸
- Nongonococcal septic arthritis is responsible for **27%** of patients presenting with a hot, swollen joint⁸
- **Prompt diagnosis** to facilitate appropriate antibiotic management of septic arthritis is essential, since **cartilage can be destroyed within days**, and in-hospital **mortality** of treated infections can be as high as **15%**⁸
- Permanent disability and increased mortality are associated with delayed presentations and diagnosis⁸

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BJI Panel Value Proposition

Investigational Use Only. Not for use in diagnostic procedures.

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Turn Around Time

- Prompt diagnosis for patients presenting with a painful, swollen, peripheral joint
- Can aid in patient triage

Small Sample Volume

- Vs current SOC and molecular sequencing
- advantageous in pediatric patients

Comprehensive Menu

- Includes the majority of pathogens that cause joint infections
- fastidious/anaerobic pathogens; AMR targets

Differential Diagnosis

- Pathogen ID can aid in differentiation of ID from non-ID conditions and help guide appropriate treatment strategies

Health Economic Benefits

- Offsetting the cost of a single revision surgery could save \$50-100K
- IV ATBX de-escalation
- Narrowing ATBX to safer alternatives

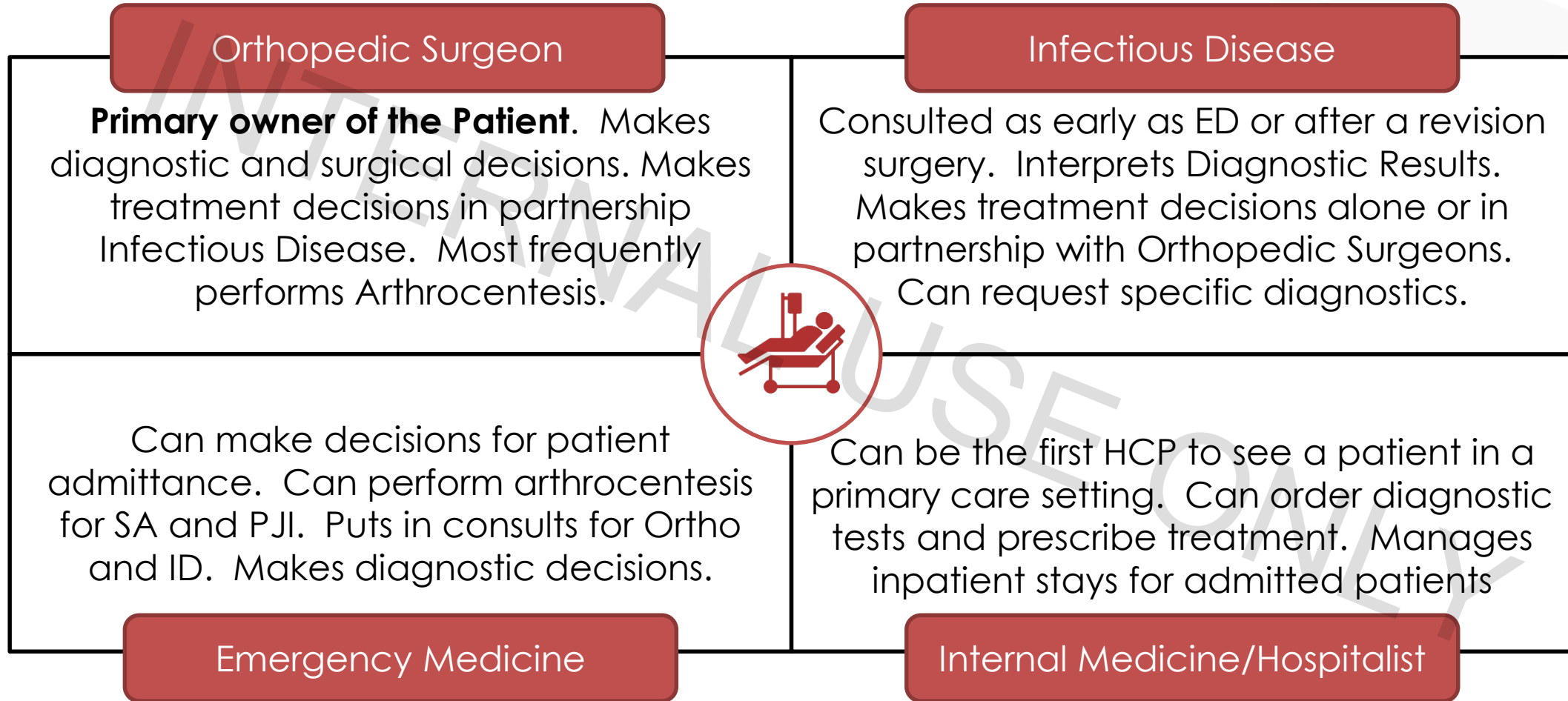
Performance

- Higher sensitivity and specificity vs SOC
- Polymicrobial detection
- Not impacted by prior ATBX Use



Patient Management Involves A Multi-Disciplinary Team Approach

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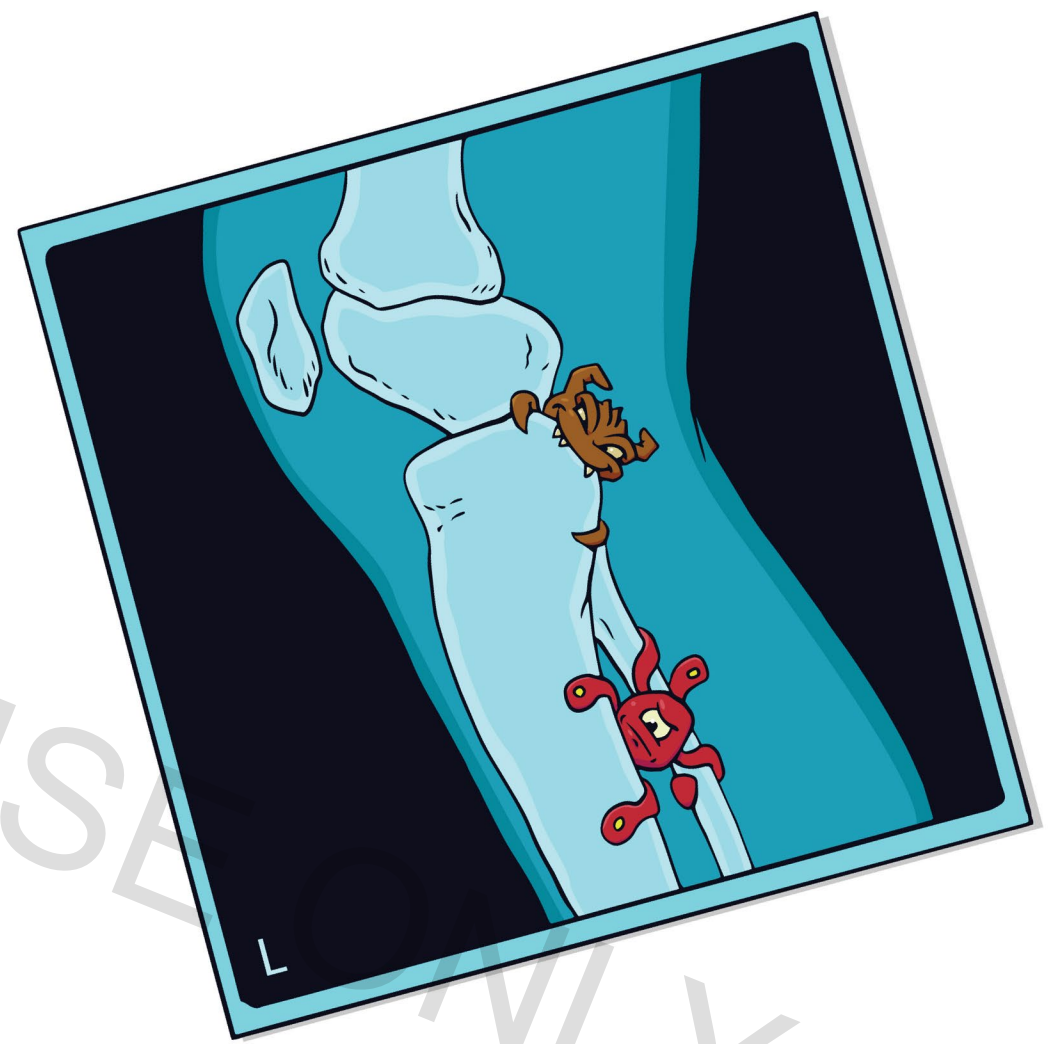
Introducing the BioFire® BJI Panel

- Panel Menu
- Specifications
- Value Proposition

INTERNAL USE ONLY



ELIMINATE THE GUESSWORK



BioFire[®] Bone and Joint Infection Panel*

1 Test. 39 Targets. ~1 Hour.

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*Investigational use only. Not for use in diagnostic procedures





The BioFire® Bone and Joint Infection (BJI) Panel

Investigational Use Only. Not for use in diagnostic procedures.

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Proposed Intended Use:

Simultaneous qualitative detection and identification of **bacteria (29)**, **yeast (2)**, and potentially associated **markers of antimicrobial resistance (8)** from synovial fluid obtained from individuals suspected to have a bone and/or joint infection such as **septic arthritis** and **prosthetic joint infections**.

BJI IUO Panel Product Characteristics

Sample Type: synovial fluid	Hands-On Time: approximately 2 minutes
Sample Volume: 0.2 mL	Time to Result: ~1 hr
Patient Type: all ages and genders	Performance: 90.6% sensitivity and 99.8% specificity
Storage Conditions: all kit components stored at room temperature	

Volume requirement is a major value proposition
SOC Requires ≥ 500 ul



BioFire® Bone and Joint Infection Panel*

1 Test. 39 Targets. ~1 Hour.

*Investigational use only. Not for use in diagnostic procedures.

GRAM-POSITIVE BACTERIA

- Anaerococcus prevotii/vaginalis*
- Clostridium perfringens*
- Cutibacterium avidum/granulosum*
- Enterococcus faecalis*
- Enterococcus faecium*
- Fingoldia magna*
- Parvimonas micra*
- Peptoniphilus*
- Peptostreptococcus anaerobius*
- Staphylococcus aureus*
- Staphylococcus lugdunensis*
- Streptococcus* spp.
 - Streptococcus agalactiae*
 - Streptococcus pneumoniae*
 - Streptococcus pyogenes*

GRAM-NEGATIVE BACTERIA

- Bacteroides fragilis*
- Citrobacter*
- Enterobacter cloacae* complex
- Escherichia coli*
- Haemophilus influenzae*
- Kingella kingae*
- Klebsiella aerogenes*
- Klebsiella pneumoniae* group
- Morganella morganii*
- Neisseria gonorrhoeae*
- Proteus* spp.
- Pseudomonas aeruginosa*
- Salmonella* spp.
- Serratia marcescens*

YEAST

- Candida*
- Candida albicans*

ANTIMICROBIAL RESISTANCE GENES

Carbapenemases

- IMP
- KPC
- NDM
- OXA-48-like
- VIM

ESBL

- CTX-M

Methicillin Resistance

- mecA/C* and MREJ

Vancomycin Resistance

- vanA/B*



Anaerobes

Fastidious

LEARN MORE: biofiredx.com

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BJI Panel Specifications

• Packaging

- **30-packs only** (Part Number: RFIT-ASY-0138 – Part number IUO pouches (for MEP): 423716)
- **No 6-packs for the moment**
 - current allocation situation due to COVID => 6 pack production halted,
 - BJI will launch only with the 30 pack configuration with the potential to revisit 6 packs in the future

• Shelf-life

- **At launch: 12 months**
- **Targeted: 24 months** (real time study until Oct 2022)

• Instruments

- **FILMARRAY® 2.0**
- **FILMARRAY® TORCH SYSTEMS**
- *Not on FILMARRAY® 1.5*

• Same workflow as other panels





Prospective Clinical Evaluation Overview

- May 2018 to March 2020
- 10 sites US, 3 sites EU
- Leftover synovial fluid specimens, unique subjects
 - Raw synovial fluid (no additives)
- Enrolled & tested within 7 days of collection
 - Refrigerated storage conditions
 - Half of enrolled specimens were frozen before testing

	Site	Location	PI
1	IU	Indianapolis, IN	Dr. Bryan Schmitt, DO
2	UNMC	Omaha, NE	Dr. Caitlin Murphy, PhD D(ABMM)
4	USC	LA, CA	Dr. Susan Butler-Wu, PhD D(ABMM)
7	HSS	NY, NY	Dr. Thomas Bauer, MD, PhD
8	HCH	Harrisburg, PA	Dr. David Craft, PhD
9	OSU	Columbus, OH	Dr. Joan-Miquel Balada-Llasat, PharmD, PhD
10	GHS	Danville, PA	Donna Wolk, PhD D(ABMM)
11	CHLA	LA, CA	Dr. Jennifer Dien Bard, PhD D(ABMM)
12	NCH	Columbus, OH	Dr. Amy Leber, PhD
13	PCH	Salt Lake City, UT	Dr. Judy Daly PhD





IUO Investigator Initiated Studies

Establish awareness of the BioFire BJI panel as the best test for determining the etiologic agent of BJIs
 Generate real world evidence to support US commercial launch
 Demonstrate clinical utility of the BJI panel for work-up of patients with a hot, swollen joint

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Site	Study Overview	Description	Timelines
EMERGENCY IDNET 12 academic affiliated urban EDs across the US PI: Mark Steele, MD	<u>Adult Septic Arthritis Study</u> Pt 1: Epidemiology/ Hypothetical Outcomes (Diagnostic yield, positivity vs SOC) Pt 2: Outcomes (Antibiotic sparing, time to narrowed therapy, change in treatment decisions, impact on surgical decision making, length of stay)	N=500 SOC: varies	Target Start: Q2 2021 Status: Contract Approved
University of Texas Pediatrics Southwestern Medical Center of Dallas PI: Laura Filkins, PhD Lawson Copley, MD, MBA	<u>Pediatric Septic Arthritis Study</u> Performance Characteristics Clinical Utility Comparator (Concordance vs 16S) Hypothetical Outcomes (achieved via retrospective chart review) Workflow (TTR, ease of use) Cost Effectiveness	N=65-100 SOC: 16s rDNA PCR	Target Start: Q2 2021 Status: Contracting Approved
Prosthetic Joint Infection Location: University of Nebraska PI: Paul Fey and Angela Hewlette	<u>Adult PJI Study</u> Performance characteristics Hypothetical Outcomes Workflow Cost Effectiveness	N=500 SOC: traditional culture	Target Start: Q1 2021 Status: Contracting in Progress



Pre-Selling vs. Educating





- From Corporate Counsel:
 - *Selling is price, volume discounts, quantities. Education is targets, what our research to date tells us about sensitivity and specificity...*
- From Regulatory:
 - *We should also be careful about claims – all of the data are preliminary until FDA signs off*
- **Don't talk Price or discounts, qualify statements about performance with the fact that this is an IUO product**



Competitive Landscape

BioFire BJI panel will be the first to market multiplex PCR test in the US

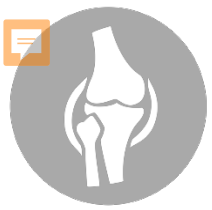
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	Available in the US	Available OUS Only
	 Synovasure Panel PJI/NSA* Microbial Antigen ID α-defensin misc biomarkers	 Orthopedic O.R. Kit Quantitative PCR + 16S NGS
System	 Unyvero Panel Multiplex PCR	 Lyfstone®: Calprotectin lateral flow biomarker test quantitative
TTR	Send Out 3-4 days panel 10 mins α-defensin	Send Out 24 hrs PCR 3-5 days NGS
Sample Volume	0.5 mL send out	2mL synovial fluid, tissue
Targets	4 species level + α-defensin	8 species level + quant +AMR
Performance	90-97.1% sensitivity 99.0-99.6% specificity	Unknown Prone to contamination
Cost	\$400	\$250
Pros	FDA Approved Backed by known Orthos High awareness Good insurance coverage P. Acnes + Staphylococcus species	FDA Approved, Backed by Rothman @TJU, direct to consumer marketing, affordable, outcomes focused, polymicrobia detection
Cons	Send Out (^TAT), Not comprehensive Cost	Send Out (^TAT) Contamination concerns skepticism towards NGS Not comprehensive PCR



Marketing Evaluation Program (MEP)

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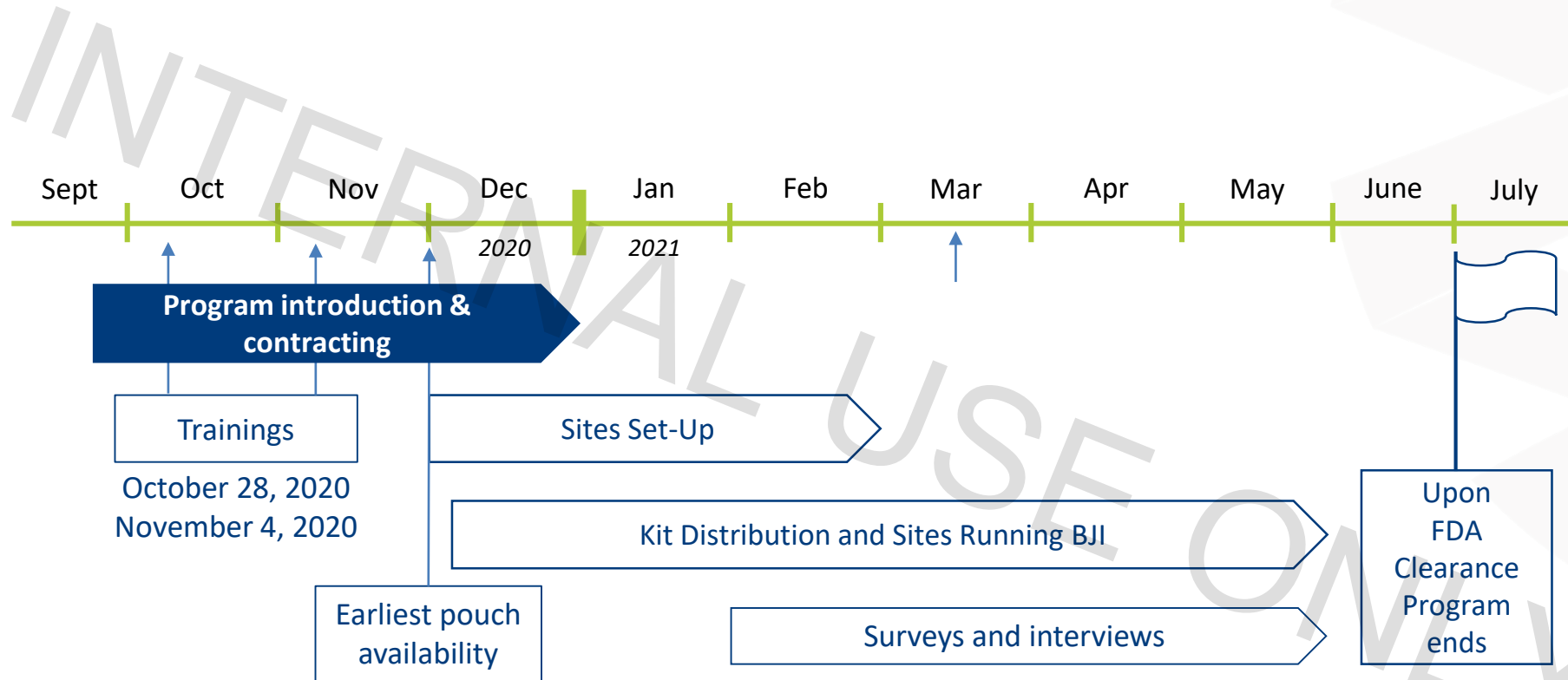
MEP Program Objectives

- Meet surgeons, infectious diseases physicians and microbiologists to understand how they see the value of the test
- Build relationships with orthopedic surgeons to increase their familiarity with BioFire
- Obtain customer feedback regarding the BJI Panel across a broad range of customer segments (existing customers and select new accounts)
- Assess how customers use and interpret test results to better inform on customer education needs
- Pressure test assumptions on panel attributes (e.g. panel strengths & limitations, discrepancies BJI & SOC, interpretation issues etc.... -> collection of FAQs)
- Collect data on customer experience and aggregate performance data vs standard of care



US BJI MEP Timelines

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US MEP Site Selection

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- **75 Sites Total**
 - 20 Non BioFire accounts- *priority given to new POC sites and stand alone orthopedic centers of excellence*
 - 65 existing FilmArray 2.0 or Torch users
- **2 kits per customer, i.e. 60 pouches**
 - Verification materials not included
- The program is limited in scope to 1 site per each field representative (TSMs, POC, SAMs, CAMs)
 - Each rep is encouraged to contract at least 1 site, but no more than 2 sites
 - Granted at a first come first serve basis
- Partner with your MEL and inside sales representatives for site identification and outreach



Ideal Participants

- Reputable local leaders **specializing in orthopedics**, preferably members of MSIS
- Preference given to **high volume BJI accounts** (>75 BJI diagnoses annually: SA+PJI)
- BioFire customers using **BCID for Synovial Fluid** to propose a more appropriate alternative
- Have **multi-disciplinary approach** to treating BJIs (vocal Orthos with good working relationship with lab and ID)
- Open to publishing and staffed to submit de-identified data
- Willingness to complete data collection surveys and/or interviews
- **Zimmer/Synovasure customers** or those with experience using other competitors such as MicroGenDx NGS send out



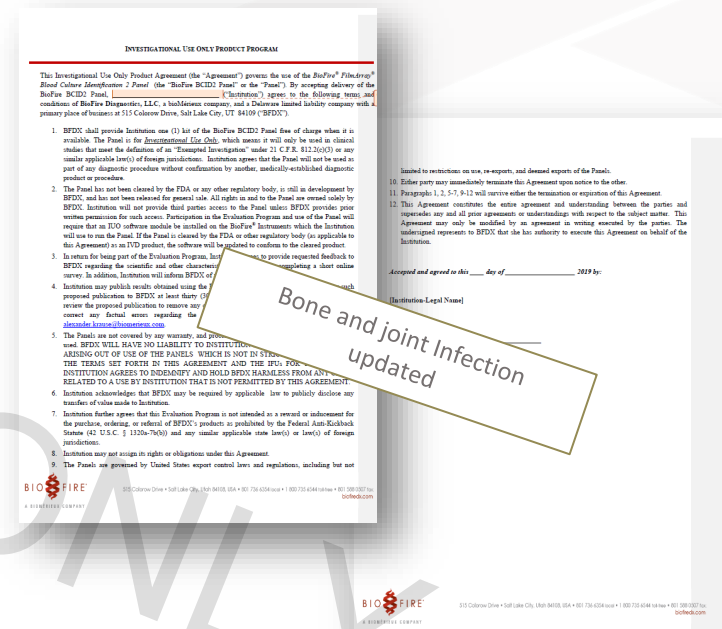
Introduce Program to Accounts

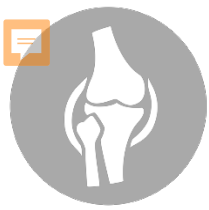
Messaging:

- They get to be **special** and **influential**
- We need their **feedback** on the product before launch

A contract will be available starting November 4th

- This is an **IUO** product
- They will have to **upgrade software before** and **after** the program
- They **cannot use** the **results** to **treat** patients
- If they want to **publish**, they are going to **check-in with us**
- They need to **fill out** our **surveys**
- There will potentially be changes to the panel during FDA review





Contracting and Enrollment

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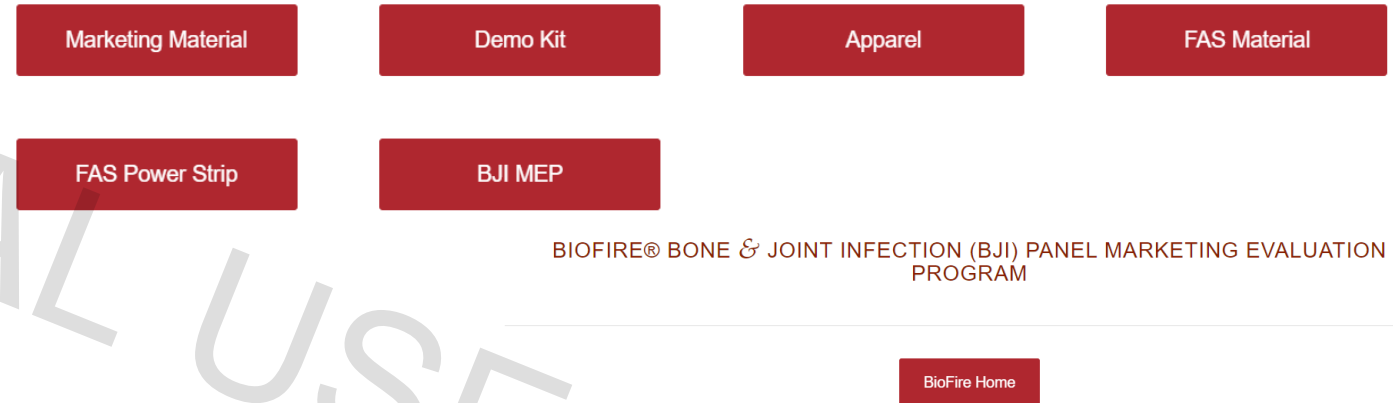
Mirror EAP program

1. Identify appropriate accounts
2. Verify selection with regional team including MEL and inside sales
3. Confirm interest in MEP participation with site
4. TSM will submit a marketing evaluation request through SMP
5. Marketing Assistants will fill out and forward an agreement to the TSM
6. TSM will get agreement executed and return it to the Marketing Assistants- **copy FAS**

marketingassistants@biofiredx.com

BIOFIRE DIAGNOSTICS' SALES STAFF

Material Orders



*Submit all evaluation requests through the Sales Manager Portal:

<https://salesmanagerportal.biofiredx.com/biofire-diagnostics-sales-team/>

This program is designed for existing BioFire® customers who are interested in the BioFire BJI Panel (Investigational Use Only) to perform an evaluation of the product pre-FDA clearance (2.0 and Torch customers, excludes 1.5). New customers participation will be granted on a case by case basis and is restricted to 20 accounts.

Prior to submission of this form the TSM should review the program with the prospective account and notify the territory FAS and MEL. We encourage site selection of high volume orthopedic treatment centers and hospitals. If you have any questions regarding site selection, please email Jenn at jennifer.baird@biofiredx.com.

When the account has a signed contract in place, please notify your FAS for IUO software installation. When scheduling installs with your FAS please keep in mind the expected time required for initial install and training (2-3 hours). If the site is a new account requiring loaner instrumentation, be sure to include this information in your correspondence.

Note that IUO product will not be available until the end of December. Once product is available, it will be sent to accounts with contracts in place and IUO software installed.

You are responsible for informing institutions that they may be subject to the Sunshine Act and obtaining any necessary information for this documentation prior to placing any order.

If there are any questions regarding this program or special needs your account may have please contact the Marketing Support Team – MarketingAssistants@biofiredx.com



SMP Form

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GENERAL INFORMATION

Sales Manager Name *

Sales Territory (Region & Number) *

FAS Name for Install & Training *

Full Legal Institution Name *

Are they a current customer? *

- Yes
 No

CUSTOMER INFORMATION

Primary Point of Contact for Evaluation (Name) *

Job Title *

Phone *

Email *

SHIPPING INFORMATION

Does Customer need N/C P.O.? *

- Yes
 No

Shipping Address *

Street Address

Address Line 2

City

State

ZIP Code

Shipping Notes:

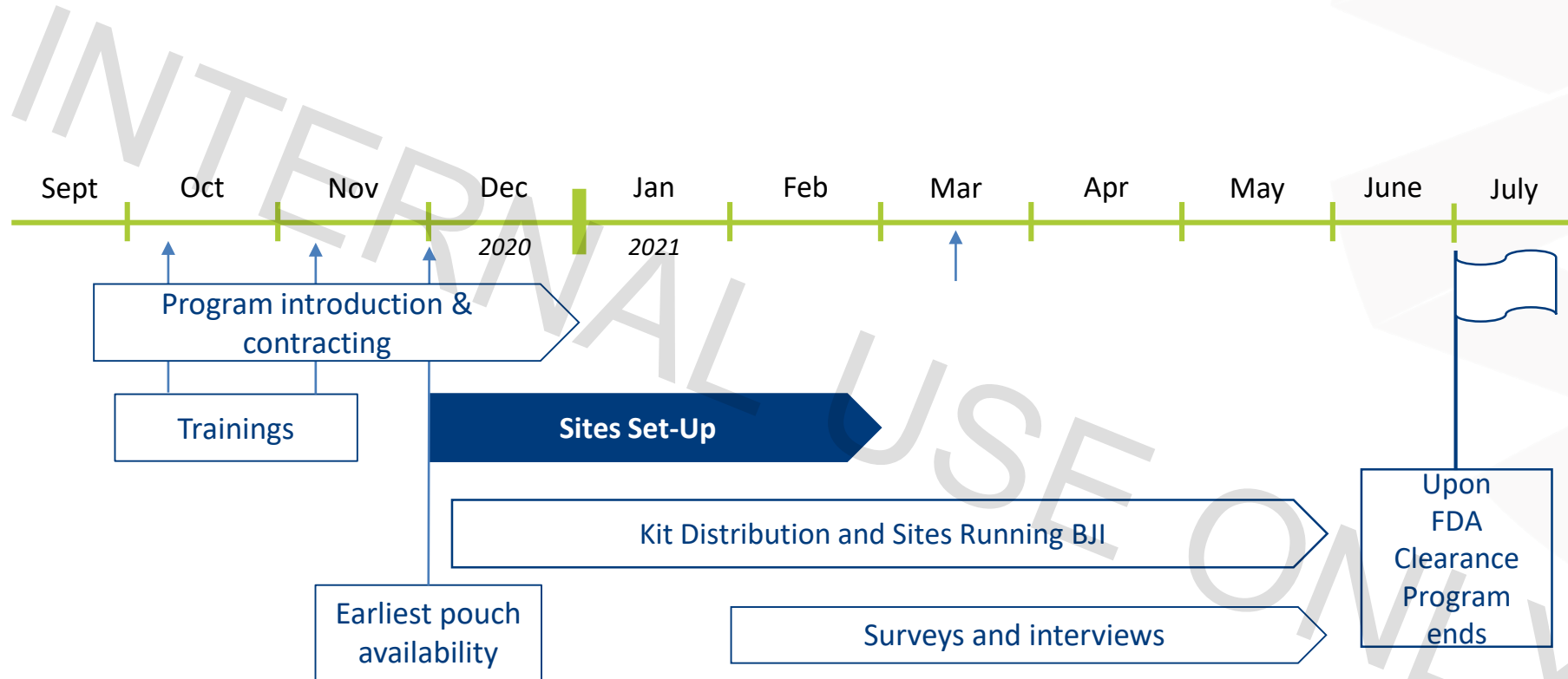
marketingassistants@biofiredx.com

*Submit all evaluation requests through the Sales Manager Portal:
<https://salesmanagerportal.biofiredx.com/biofire-diagnostics-sales-team/>



US BJI IUO MEP

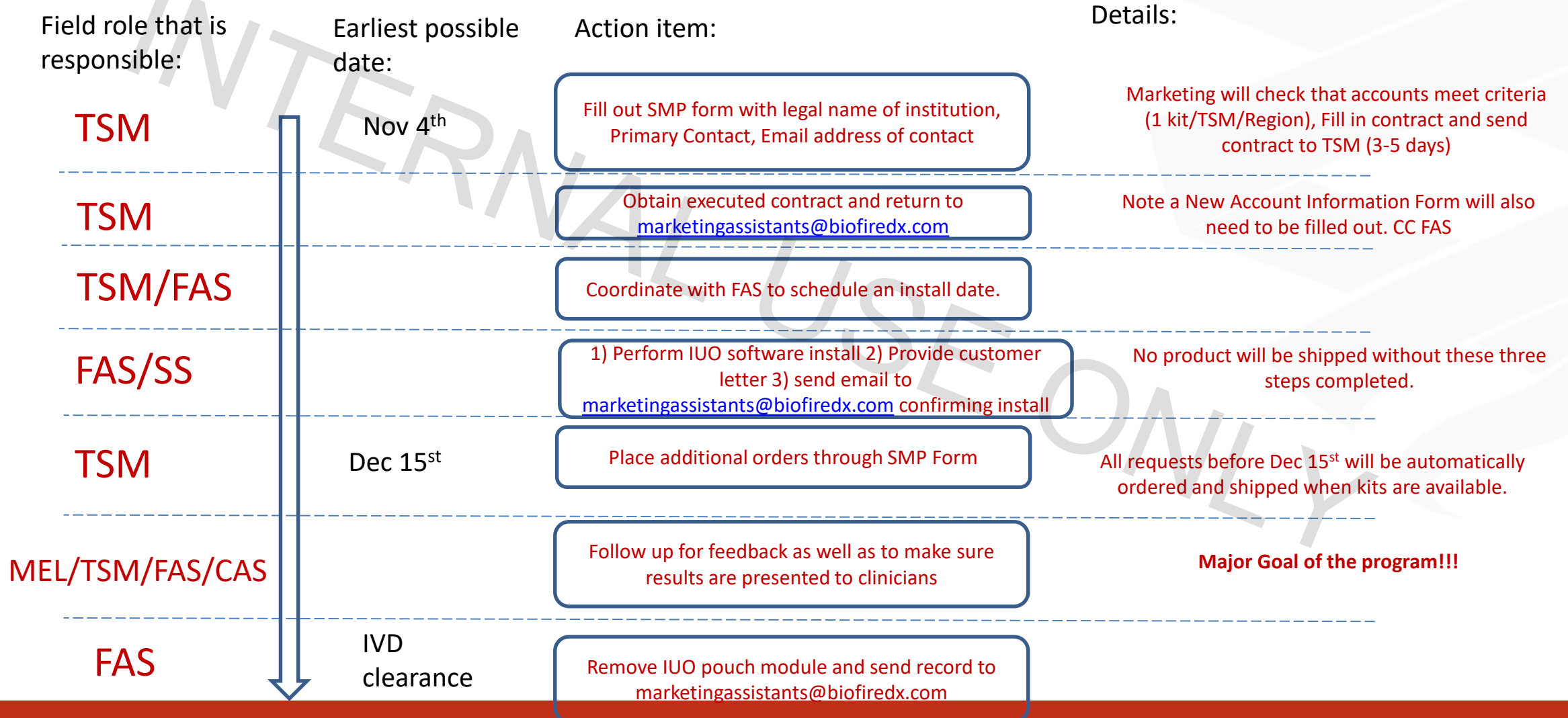
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Workflow for Enrolling an Account

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Site Set Up- Software Installation

1. There is no Core Software update
 - Customers who have not upgraded to the newest IVD Core Software can do so via e-labeling
 - A Core Software update is not required to run BJI
2. The MEP does not support LIS connectivity
3. Only 2.0 and Torch instruments are supported
4. Installation of IUO Pouch Module software is needed
 - FAS is required to notify marketingassistants@biofiredx.com that IUO software has been installed prior to kit distribution.
 - Upload using a USB stick again [web-based installation not possible]
 - Drop off Folder with customer letter during in person visit



IUO FOLDER

ELIMINATE THE GUESSWORK



BioFire® Bone and Joint Infection Panel*

Panel Menu:

GRAM-POSITIVE BACTERIA

Acinetobacter baumannii complex
Candida parapsilosis
Candida lusitana
Candida guilliermondii
Enterococcus faecalis
Enterococcus faecium
Flavobacterium meningosepticum
Parvimonas micra
Peptostreptococcus
Peptostreptococcus anaerobius
Staphylococcus aureus
Staphylococcus epidermidis
Staphylococcus saprophyticus
Staphylococcus pneumoniae
Staphylococcus pyogenes

GRAM-NEGATIVE BACTERIA

Bacteroides fragilis
Citrobacter
Enterobacter cloacae complex
Escherichia coli
Haemophilus influenzae
Klebsiella pneumoniae
Klebsiella aerogenes
Moraxella pneumoniae group
Morganella morganii
Neisseria gonorrhoeae
Proteus spp.
Pseudomonas aeruginosa
Serratia spp.
Serratia marcescens

YEAST

Candida spp.
Candida albicans

ANTIBIOTIC RESISTANCE GENES

AMP^r
APC
NDM
OXA-48-like
VM
ESBL
CTX-M
Multidrug Resistance mecA/C and MREJ
Vancomycin Resistance vanA/B

39 TARGETS
~1hr

INTERNAL USE ONLY



BioFire® Bone and Joint Infection Panel* 

The Right Test, The First Time.
Synchromic Testing:



For assistance please contact our customer technical support team at:
 support@biofire.com
 801-736-6341 option 5
 1-800-735-6944

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The BioFire BJI Panel Evaluation Program Guidelines

Dear Participant,

Thank you for evaluating the BioFire® Bone and Joint Infection (BJI) Panel. This panel tests an anticipated 39 targets, including 8 antimicrobial resistance genes, from synovial fluid. Please take a moment to read through the Evaluation Program Guidelines before you begin running pouches.

Evaluation Program Objective

The goal of this program is for you to evaluate the BioFire BJI Panel in your laboratory and assess how the workflow and results of this panel compare with your current testing procedures. It is important to get input from a broad range of stakeholders at your institution on how this panel will change practices and workflow. We suggest forming an evaluation team that includes relevant clinician groups (Orthopedic Surgeons, Infections Disease, and Pharmacy) as well as Laboratory Directors, Managers, and Technologists. You will be asked to complete a short online survey about your experience with the panel. You will also be asked to report de-identified sample level data to evaluate how the panel compares to the standard of care.

Investigational Use Only

The BioFire BJI Panel is for Investigational Use Only (IUO). Do not use results from this panel to make patient care decisions.

Material

The BioFire BJI Panel IUO kits contain 60 reagent pouches (PLACEHOLDER TEXT) to be run on your existing BioFire® FilmArray® System instrument. If you are new to BioFire, you will be receiving an instrument on loan in addition to reagent kits. Verification material will not be supplied.

Panel Overview

The BioFire BJI Panel uses nested multiplex PCR, followed by melting-curve analysis, to detect select organisms and antimicrobial resistance (AMR) genes in synovial fluid samples of patients with suspected bone and joint infections. The panel identifies specific gram-positive, gram-negative, yeast, and AMR genes as shown in Figure 1. The intended use of the BioFire BJI Panel is to aid in timely diagnosis of bone and joint infections via simultaneous detection and identification of etiologically associated bacteria and fungi in synovial fluid derived from individuals suspected of septic arthritis or prosthetic joint infections.

Sample Recommendations

The sample requirement for the BioFire BJI Panel is 0.2 mL of synovial fluid.



515 Colorow Dr. | Salt Lake City, Utah | 84108 | 801-736-6354



Figure 1. The BioFire BJI Panel proposed menu

GRAM-POSITIVE BACTERIA

Anaerococcus prevotii/vaginalis
Clostridium perfringens
Cutibacterium avidum/ granulorum
Enterococcus faecalis
Enterococcus faecium
Finegoldia magna
Parvimonas micra
Peptoniphilus
Peptostreptococcus anaerobius
Staphylococcus aureus
Staphylococcus lugdunensis
Streptococcus spp.
Streptococcus agalactiae
Streptococcus pneumoniae
Streptococcus pyogenes

GRAM-NEGATIVE BACTERIA

Bacteroides fragilis
Citrobacter
Enterobacter cloacae complex
Escherichia coli
Haemophilus influenzae
Kingella kingae
Klebsiella aerogenes
Klebsiella pneumoniae group
Morganella morganii
Nisseria gonorrhoeae
Proteus spp.
Pseudomonas aeruginosa
Salmonella spp.
Serratia marcescens

YEAST

Candida spp.
Candida albicans

ANTIMICROBIAL RESISTANCE GENES

Carbapenemases
IMP
KPC
NDM
OXA-48-like
VIM

ESBL
CTX-M

Methicillin Resistance
mecA/C and *MREJ*

Vancomycin Resistance
vanA/B

Software Requirements

In order to run the BioFire BJI Panel IUO reagent pouches on the BioFire® System, the BioFire BJI Panel IUO software module will need to be installed on your existing BioFire® FilmArray® 2.0 or BioFire® FilmArray® Torch System instrument. Your local Field Application Specialist will be in touch with you to install the module. The software update and/or addition of the BioFire BJI Panel IUO software will not affect the other BioFire® FilmArray® Panels you may be running. Therefore, BioFire is not recommending any additional verification. If you are new to BioFire, your Field Application Specialist will be responsible for installing your loaner BioFire instrument in addition to the IUO software.

Reporting

When the BioFire BJI Panel run is completed, the system outputs a detection summary showing which organisms were "Detected" or "Not Detected". Additionally, applicable AMR genes will be displayed for the "Detected" organisms with an indication if these genes were "Detected" or "Not Detected". If the report displays "N/A", the AMR gene was not reported because an organism associated with the gene was not detected. Figure 2 details the conditional reporting structure of the AMR genes.



Discrepancy Analysis and Support

If you obtain a discrepant result with your stand of care when running the BioFire BJI panel, you have the option to retain the sample and report the discrepancy to BioFire technical support. A representative may ask for more information or for the sample to be sent back to BioFire. BioFire is dedicated to providing the best customer service available. If you have questions, concerns, or additional feedback on the panel, please do not hesitate to reach out to us.

BioFire Customer Technical Support

Email: support@biofiredx.com
Phone: 1-800-735-6544, Option 5

Program Completion

If you used a loaner instrument, the program duration shall be limited to less than 90 days, and your Field Application Specialist will be in touch to facilitate the instruments return to BioFire. BioFire will notify all program participants when the BioFire BJI Panel is cleared by the Food and Drug Administration (FDA) for In Vitro Diagnostic (IVD) use. The program will end when you receive this notice or June 2021, whichever is sooner. Upon completion of the program, your Field Application Specialist will be in touch with you again to remove the BioFire BJI Panel IUO software from your system or to upgrade your system to the IVD version of the software if you choose. Please schedule a time to remove or upgrade the software within 90 days of program completion.

Thank you for your participation in this program and for the valuable feedback you are providing!



Figure 2. Conditional reporting of AMR genes.

Antimicrobial Resistance Gene(s)	Organism(s)
<i>mecA/C</i> MREJ(MRSA)	<i>Staphylococcus aureus</i>
<i>vanA/B</i>	<i>Enterococcus faecalis</i>
OXA-48-like	<i>Citrobacter</i> <i>Enterobacter cloacae</i> complex <i>Escherichia coli</i> <i>Klebsiella aerogenes</i> <i>Klebsiella pneumoniae</i> group
CTX-M IMP KPC NDM VIM	<i>Citrobacter</i> <i>Enterobacter cloacae</i> complex <i>Escherichia coli</i> <i>Klebsiella aerogenes</i> <i>Klebsiella pneumoniae</i> group

CUSTOMER LETTER




ROAD MAP

BioFire® Bone and Joint Infection (BJI) Panel

INVESTIGATIONAL-USE-ONLY EVALUATION PROGRAM

STEP-BY-STEP GUIDE

- 
- 1 Start your engines! Get revved up to meet the new BioFire BJI Panel.
 - 2 Greet your BioFire Field Application Specialist, who will visit you to install the BioFire BJI Panel IUD software on the BioFire® FilmArray® System.
 - 3 Develop a testing plan to evaluate the BioFire BJI Panel for patients with suspected bone and joint infections.
 - 4 Receive BioFire BJI Panel IUD reagents. You will be receiving 2 kits (60 pouches).
 - 5 Test a selection of synovial fluid samples with the BioFire BJI Panel IUD kit. (IUD test results may not be used to guide patient care).
 - 6 Gather your BioFire BJI Panel Multidisciplinary Team to discuss the panel's performance.
 - 7 Send questions, discrepancies, and additional feedback regarding your experience with the BioFire BJI Panel to BioFire Customer Technical Support.
 - 8 Welcome your BioFire Field Application Specialist for a second visit to uninstall the BioFire BJI Panel IUD software.
 - 9 Provide your feedback by completing two surveys including a user experience survey and a data collection survey.



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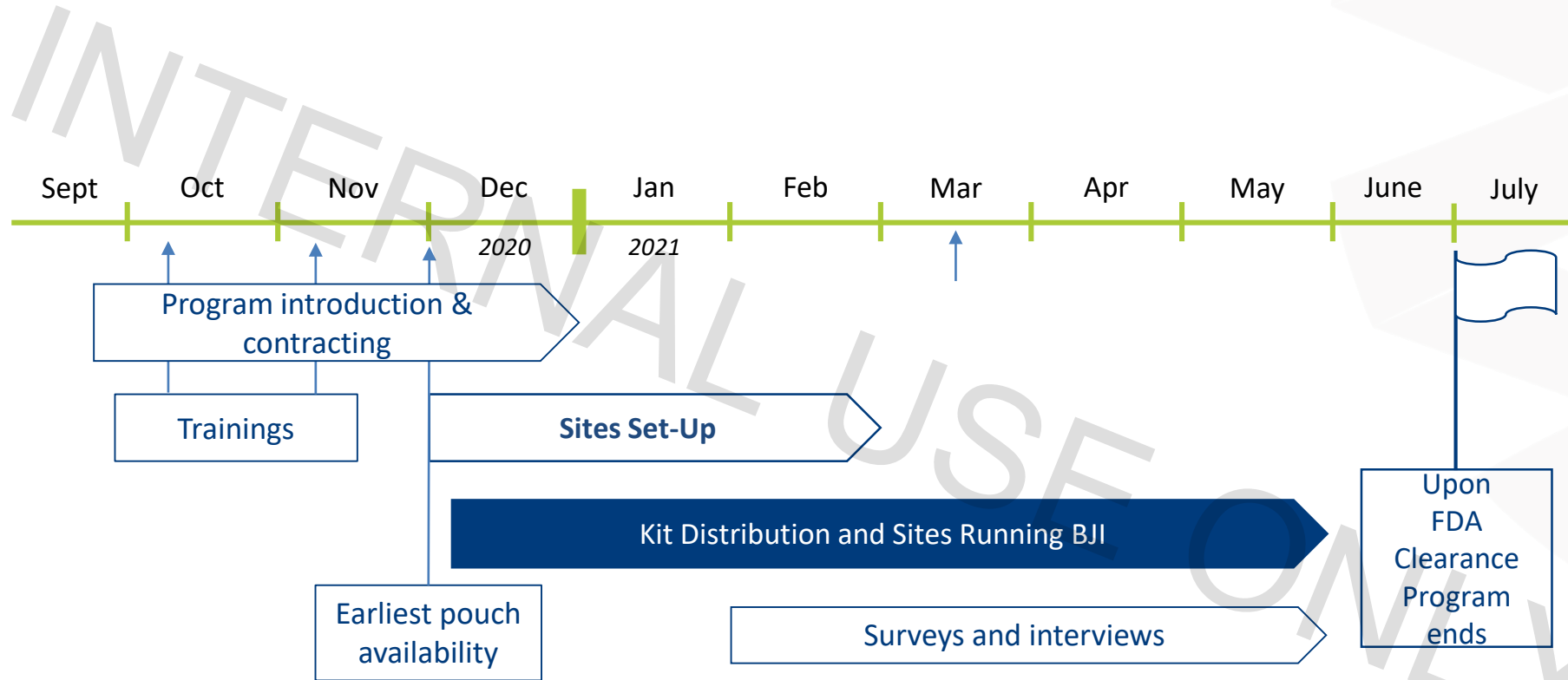
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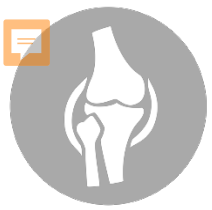
INTERNAL USE ONLY



US BJI IUO MEP

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Distributing Kits to Participants

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Earliest available date: December 15st

1. Marketing Assistants will fill all existing orders made prior to Dec 15st
 - Participants must have signed contract
 - FAS will have notified Marketing Assistants that IUO software is installed
2. Subsequent orders will be filled as they arrive after Dec 15st
 - A maximum of two kits/site (60 pouches) is allowed
3. TSM/FAS/MEL follow up visit
 - Get results in front of clinicians
 - Try to get Surgeons, Physicians & Lab to 1 meeting at the end (big accounts)
 - Encourage participation in online surveys (at least 1 per site) after the MEP



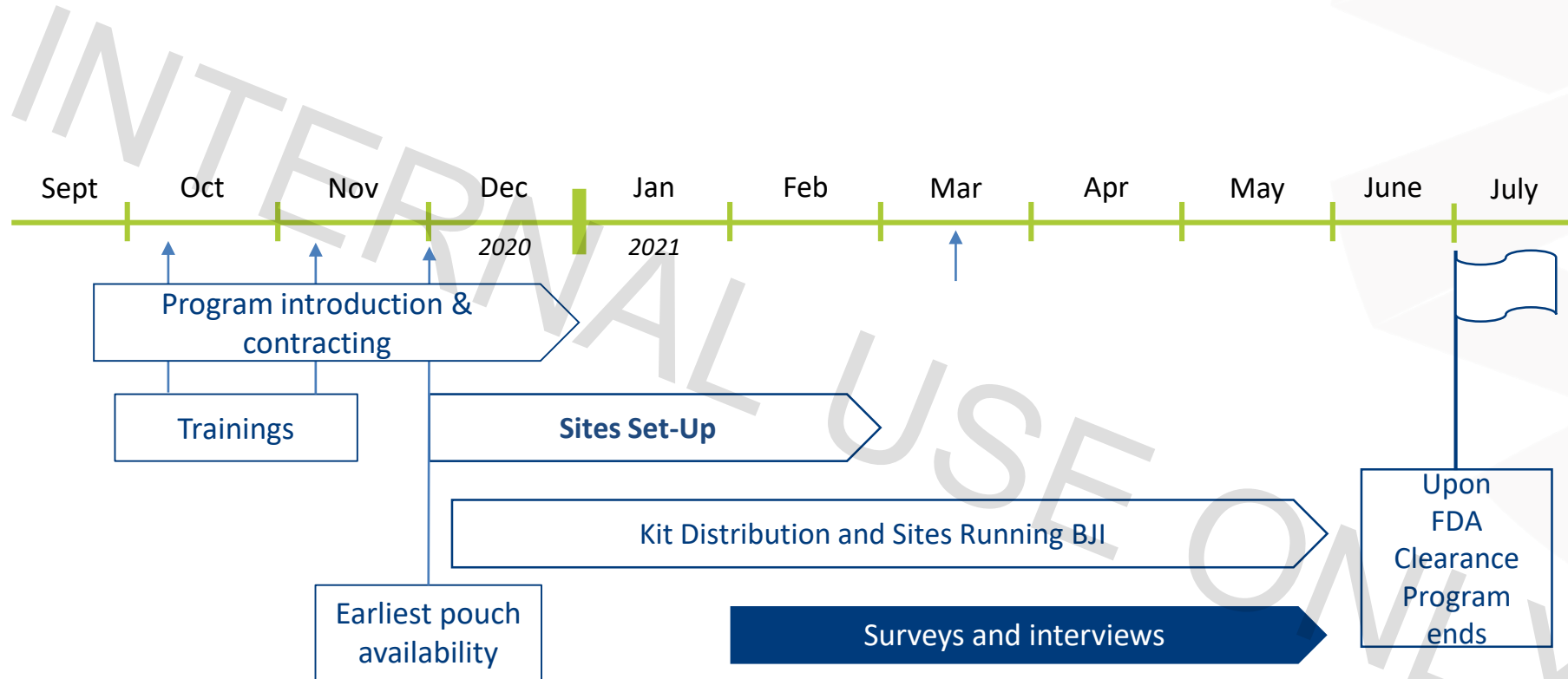
Discrepancy Testing

- Participants can call BioFire Customer Support for feedback, complaints, and inquires.
 - CASs will be able to provide preliminary investigations into discrepancies, technical issues, and control failures.
 - Complaint Investigations will not be performed.
 - However, discrepancy testing will be performed at BioFire discretion
- **Please forward all complaints to Customer Technical Support**
- **CASs can provide survey links**
- **Pouch credits will not be provided**



US BJI IUO MEP

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US BJI IUO MEP Surveys and Interviews

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● Market research surveys (Online)

- Will be sent to primary MEP account automatically **after completion** of the MEP
- Can also be sent to non-primary contacts by Sales or Marketing
- Will **not** include patient-related questions
- Survey has tailored questions for both lab members and clinicians
- The overall goal is to better understand the product value proposition to influence marketing collateral and to craft effective responses to FAQs/objection handling



1. **Learn about workflow, issues, study ideas etc...**
2. **Identify training / Marketing Material needs for BJI launch**
3. **Collect FAQs**
4. **Candidates for poster, UGM-speakers, Webinar speakers, Symposium etc...)**

● Medical Affairs Survey (Online)

- Will take about 10 mins, requires EHR access
- De-identified sample level questions
- Findings can lend to aggregate consortium publications and as a basis for conducting scientific advisory boards
- The overall goal is to better understand performance characteristics in relation to SOC and to assess clinical utility





BJI MEP Data Collection Tool

BioFire BJI Panel Result						Sample Information			
Sample	BioFire BJI Panel Result Detections	BioFire BJI Panel Result Detections (AMR)	BioFire BJI Panel Results (additional detection)	BioFire BJI Panel Result (Additional AMR detection)	Additional BioFire BJI Result (>3) (Free Text)	Subject Age	Sample Source	Joint Ty	Collection Method
1									

Synovial Fluid Analysis/Culture							
Synovial Fluid Culture Result	Synovial Fluid enriched in blood culture bottles? (y/n)	Synovial Fluid Isolate #1 ID (Free Text)	Synovial Fluid Isolate #1 AST (Free Text)	Synovial Fluid Isolate #2 ID (Free Text)	Synovial Fluid Isolate #2 AST (Free Text)	Synovial Fluid Isolate #3 ID (Free Text)	Synovial Fluid Isolate #3 AST (Free Text)

Additional Tests Performed														
Blood Cultures Performed? (y/n)	Isolate #1 identified by positive blood culture (free text)	Isolate #1 AST (free text)	Isolate #2 identified by positive blood culture (free text)	Isolate #2 AST (free text)	Isolate #3 identified by positive blood culture (free text)	Isolate #3 AST (free text)	Tissue Culture Performed (y/n)	How many tissue samples cultured?	Isolate identified from tissue culture #1 (free text)	How many tissues was Isolate #1 identified from? (free text)	Isolate identified from tissue culture #2 (free text)	How many tissues was Isolate #2 identified from? (free text)	Isolate identified from tissue culture #3 (free text)	How many tissues was Isolate #3 identified from? (free text)

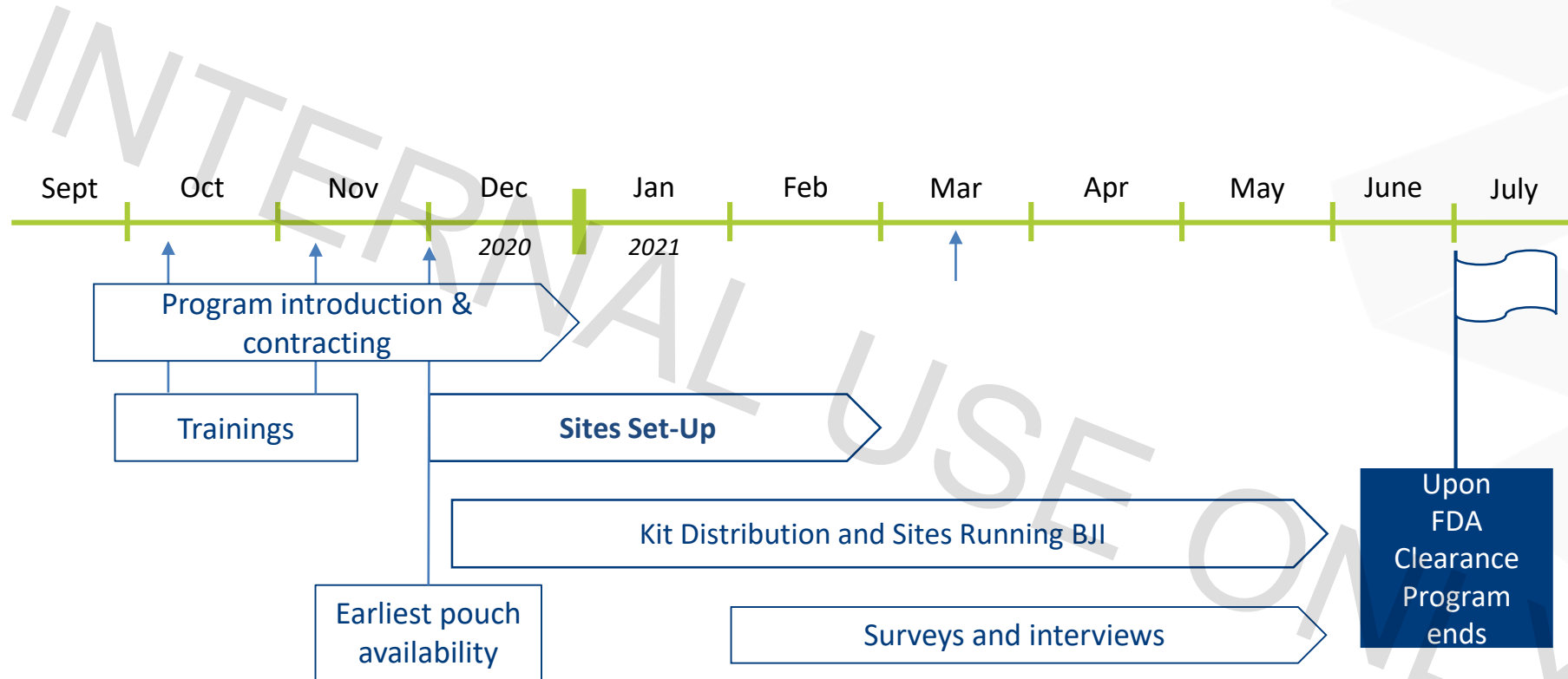
Please list additional molecular testing performed (PCR, 16S, NGS) and if for specific targets (free text)

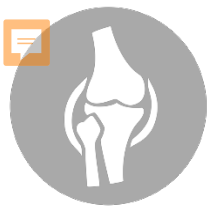
Results from additional molecular testing (free text)



US BJI IUO MEP

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Upon Clearance: Program Ends

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- FAS to perform a site visit to every participating account to remove IUO software from site.
- FAS must contact marketingassistants@biofiredx.com when the software is removed from a site
- All media (USBs) containing IUO pouch modules must be accounted for by BioFire QA team (unique tracking number)



US BJI IUO MEP Next steps

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- **BJI Medical Training on November 4th**
- **Confer with your region, MEL, CAM, SAM, and Insides sales to identify your Bone and Joint Infection MEP accounts**
- **Once identified, submit interest form through the SMP with final selection**
- **Documents available on showpad and the SMP**
 - Customer Letter, MEP step by step Guide, BJI panel IUO Quick Guide, Contract
- **Contract to be completed and sent to marketingassistants@biofiredx.com**
- **Get the contracts signed & the pouch software installed**
- **Start the Evaluation !**



Questions?

- **Presenter:** Jenn Baird
 - Jennifer.Baird@biofiredx.com
 - **Call/Text:** (385)-280-9547
- **Moderator:** Cynthia Levinthal
- You may chat to everyone or me privately to ask your questions...

