STAR WEST

A TECHWELL EVENT

## W15

Agile Testing
Wednesday, October 3rd, 2018 3:00 PM

# Compliance and Agility-How It Can Be Done


**Presented by:**

## Aprajita Mathur

**Guardant Health**


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# Aprajita Mathur

Aprajita Mathur is a Bioinformatics Software Quality Assurance Manager with a engineering background in Bioinformatics. She has more than 10 years of software testing experience and over 5 years of testing in a compliance environment. She has worked as a manual and automation tester on a wide range of products like instrument software, LIMS, web-applications and integrated solutions which are used in the fields of agriculture, transplant genomics, forensics and oncology. Currently she leads the Bioinformatics Software Quality Assurance team at Guardant Health, which builds the world's leading comprehensive liquid biopsy. This non-invasive tool for accessing and sequencing tumour DNA is used by thousands of oncologists to help tens of thousands of advanced cancer patients. In her spare time, she loves to spend time with her family and work on her bucket list of "Crazy Things", this includes activities outside her comfort zone like skydiving or quilting.

# Compliance and Agility
# How it can be done !

APRAJITA MATHUR

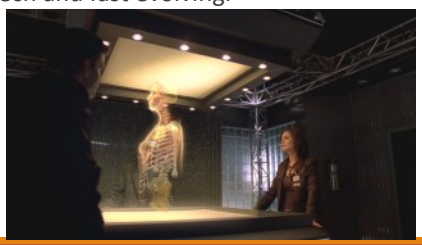
## Agenda

- The Project at Hand
- AgileBut
- What we uncovered
- What we improved
- What we further improved
- What worked

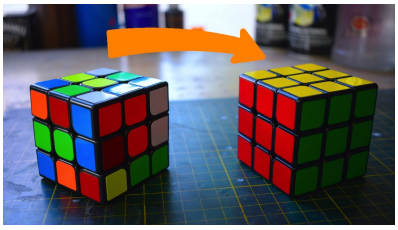
Heard of Forensics ?

## The CSI Effect

- DNA evidence wraps up every case.
- There is enough evidence at all crime scenes.
- Tests are done in hours and cases are solved in a few days.
- Criminals always make mistakes and leave evidence.
- Forensic labs are high tech and fast evolving.
- Super Science.



# Basics Forensic Analysis

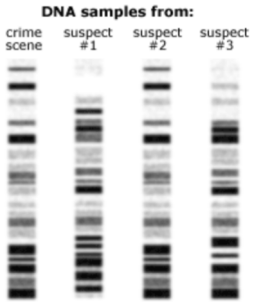


- DNA contains ATGC Nucleotides
- Short Tandem Repeats (STR) => (3-4 Nucleotides) n
- No of repeats within STR = Allele
- D7S820 => Chr 7 , (GATA) n = 5-16 , 12 allele's
- D7S820 (alleles 10 and 15) , one from each parent.
- 12 Allele Combinations => 78 different possible genotype 12 homozygotes and 66 heterozygotes.

# Analyzing Data

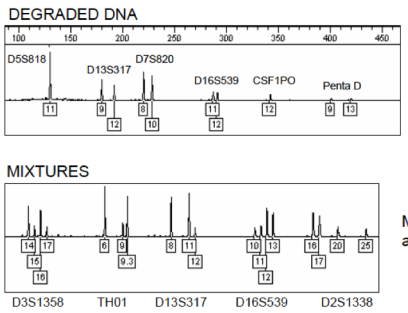
| STR Locus | Evidence Sample | Suspect A | Suspect B | Suspect B's Genotype Frequency for Each STR |
|---|---|---|---|---|
| D3S1358 | 15, 17 | 17, 17 | 15, 17 | 0.13 |
| vWA | 15, 16 | 18, 19 | 15, 16 | 0.22 |
| FGA | 23, 27 | 21, 23 | 23, 27 | 0.31 |
| D8S1179 | 12, 13 | 14, 15 | 12, 13 | 0.34 |
| D21S11 | 28, 30 | 27, 30.2 | 28, 30 | 0.06 |
| D18S51 | 12, 18 | 14, 18 | 12, 18 | 0.11 |
| D5S818 | 13, 13 | 9, 12 | 13, 13 | 0.29 |
| D13S317 | 12, 12 | 12, 12 | 12, 12 | 0.21 |
| D7S820 | 10, 11 | 9, 10 | 10, 11 | 0.26 |
| CSF1PO | 8, 11 | 11, 12 | 8, 11 | 0.18 |
| TPOX | 7, 8 | 8, 8 | 7, 8 | 0.30 |
| THO1 | 9.3, 9.3 | 6, 9.3 | 9.3, 9.3 | 0.38 |
| D16S539 | 9, 13 | 11, 12 | 9, 13 | 0.10 |

Source 1 : https://www.nature.com/scitable/topicpage/forensics-dna-fingerprinting-and-codis-736
Source 2: https://evolution.berkeley.edu/evolibrary/news/060301_crime




When forensic scientists examine DNA in the lab, each sample appears as a unique sequence of dark bars. Patterns of bars are compared to find a match. In the hypothetical example shown here, it looks like suspect #2 left some DNA at the crime scene.

# Analyzing the Real Data

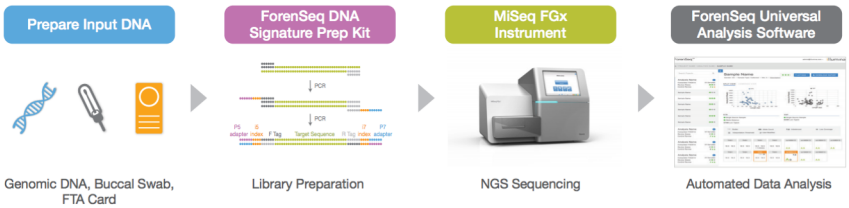



Loss of signal at larger size loci

More than two alleles at multiple loci

Source : Butler, J.M. (2004) Short tandem repeat analysis for human identity testing. Current Protocols in Human Genetics, John Wiley & Sons, Hoboken, NJ, Unit 14.8, (Supplement 41), pp. 14.8.1-14.8.22

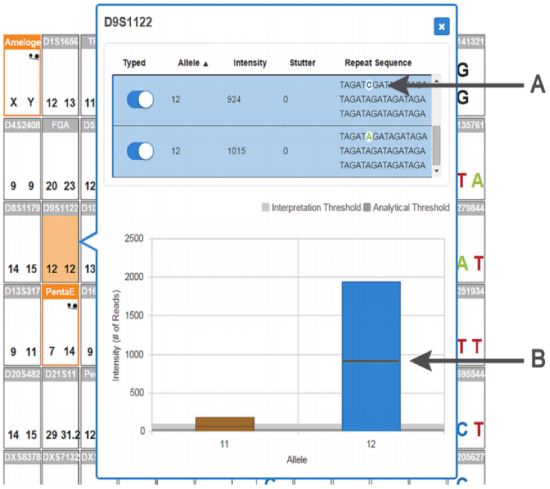
# MiSeq™ FGx Forensic Genomics System




Complete DNA-to-Data solution – 200+ Markers , 96 Samples

| Feature | Number of Markers[a] |
|---|---|
| Global Autosomal STRs | 27 |
| Y-STRs | 24 |
| X-STRs | 7 |
| Identity SNPs | 95 |
| Phenotypic SNPs[b] | 22 |
| Biogeographical Ancestry SNPs[b] | 56 |

**For Research Use Only. Not for Use in Diagnostic Procedures.**




# ForenSeq Universal Analysis Software

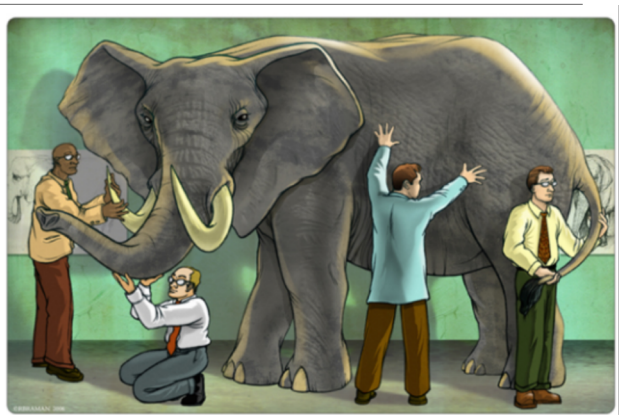
- Seamless Integration with MiSeq™ FGx
  - Kick off your run and see analysis results
- Advanced analysis
  - Automated sample comparison
  - Probability information from population statistics
  - Phenotypic and Ancestry Prediction
- User Settings: Analysis Parameters, Assay Kit Management, Custom Population Databases
- Multiple Reports

# Recent News

- Identical Twins
- Golden State Killer

# We Are Pro-Agile !

- We do Agile "Development"
- Phase Exists
- Multiple Internal Stakeholders
- My agile is the agile



# Acknowledge the Elephant

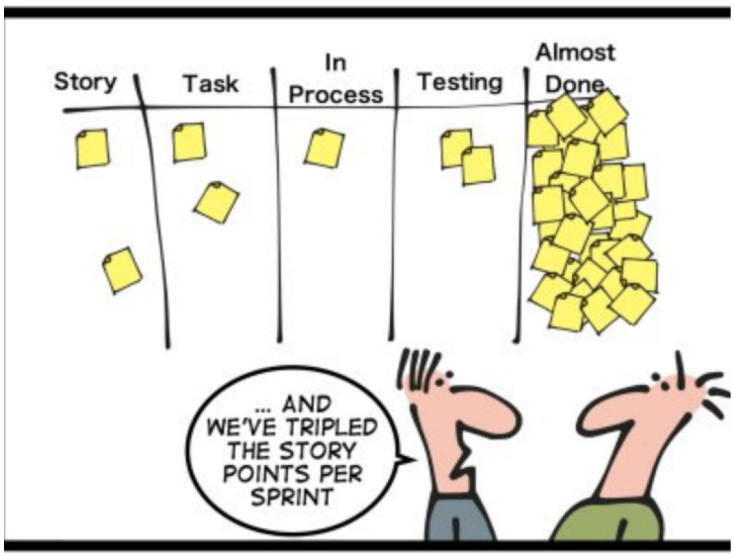
- Artifacts – Business Level
- Estimate , Track and Account
- Account for Internal Timelines
- One Point of Contact (POC)
- Scrum Master (SM)
- Product Owner (PO)
- Train and get a "Our Agile" Leveling.

# Pre-Work and Alignment

- Customer at heart
- Goal for the Sprint
- Acceptance Criteria (AC) for sprint
- Ready to Negotiate at Planning
- All Leads Involved (Dev , PO , SM , Test and UX)

# Keep it Real

- Demo's
- Standup's and Retrospectives
- Too much/less on the sprint
- Acknowledge you require to do this work (Again) – Team Level
- Code It vs Quality vs Documentation ? (AC)




# Ship What ?

- Just Requirements
- Just Code
- Just Tests
- Just Docs
- Just Enough Defects !

# Build It like you mean it (DOD)

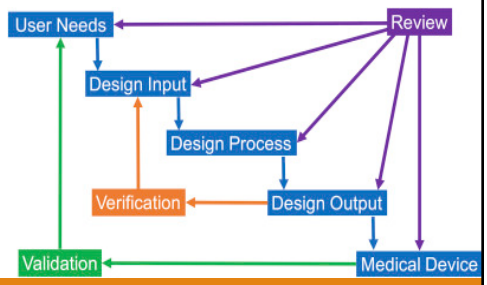
- Get the team Involved
- Automation – Build it in
  - Return on Investment (ROI)
  - Leveraged UX Workflows
  - Trace
- Manual
  - Maintenance
  - Test Steps and Modularization
- UX and UAT

# Lets Talk Regulations

- I have never done Agile with them
- Lets just do what works please
- FDA does not allow Agile

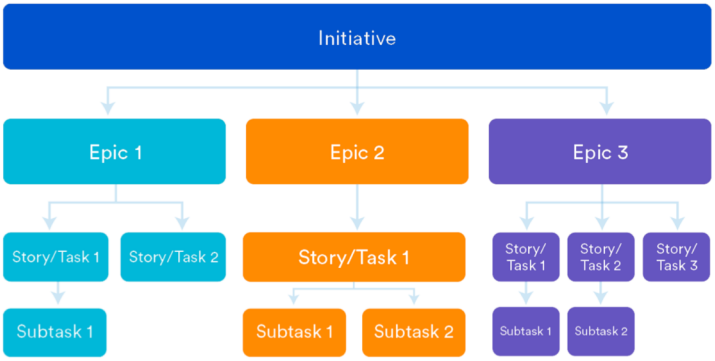
*"CONCURRENT ENGINEERING : The Waterfall model's usefulness in practice is limited.* The model does apply to the development of some simpler devices. However, for more complex devices, a concurrent engineering model is more representative of the design processes in use in the "FDA 21 CFR 820.30

- You cant document like that , its not acceptable !
- Plan , Requirements , Designs , Trace , Risk Management , Control Management (SOUP and COTS) , Traceability , Verification and Validation.
- Least Burdensome Approach



# The Balance

- Clarify AS MUCH AS YOU CAN (AC)
- Definition of Done – hard mark
- Defects
- Documents
- Data **
- Share the work !!!!
- Others QA and Internal activities




# Optimize

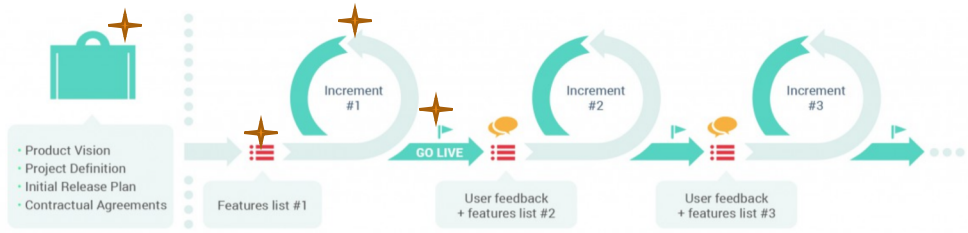
- Behavioral Changes
- Features > Epic > Stories > Tasks (Record and Trace )
- Estimations
- Planning (Review and Improve)
- Investigate (Control , SOUP /COTS)
- Demo's (Risk , Review , Plan )
- Bug Scrub (Risk, Plan, Track)
- Document as you go

Source : https://www.atlassian.com/agile/project-management/epics-stories-themes

# Remember the Elephant ?

- Understanding their pain points – GO AGILE !
- Internal vs External
- Maintaining a Backlog and Prioritization
- User Acceptance Testing (UAT) before UAT

# RECAP




- Define and Refine Backlog
- Early Involvement of All , Including Customers
- Definition of AC and Done – All Levels
- Standards and Needs
- Get Involved as a TEAM
- Feedback : Team and Process
- Optimize Tools => Export and Done
- Quality Over Quantity !

# Results

- Streamlined Process and Team Interactions
- Ready with what's needed to make it
- Build as you go strategy – allows to ship with just one/two hardening sprint
- API Automation (End-End, Integration, Module)
  - New Data and Features
  - EOD , we know if its broken
- Manual Testing
  - Anyone can run it!
  - Modular
- Reproducibility Between Environments
- Proposed new Strategies for Internal SDLC

## Thank You

Joe , Cydne , Kirby , Anthony , Chris , Dan , Van , Kevin , John , Carey , Stephanie , Sandhya , Jude , Jay , Felix , Jocelyn , Veeresh , Mitchel .

* In no order of Importance :D

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## Questions

# References


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- http://agilemethodology.org
- https://www.fda.gov/medicaldevices/digitalhealth/softwareasamedicaldevice/default.htm
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