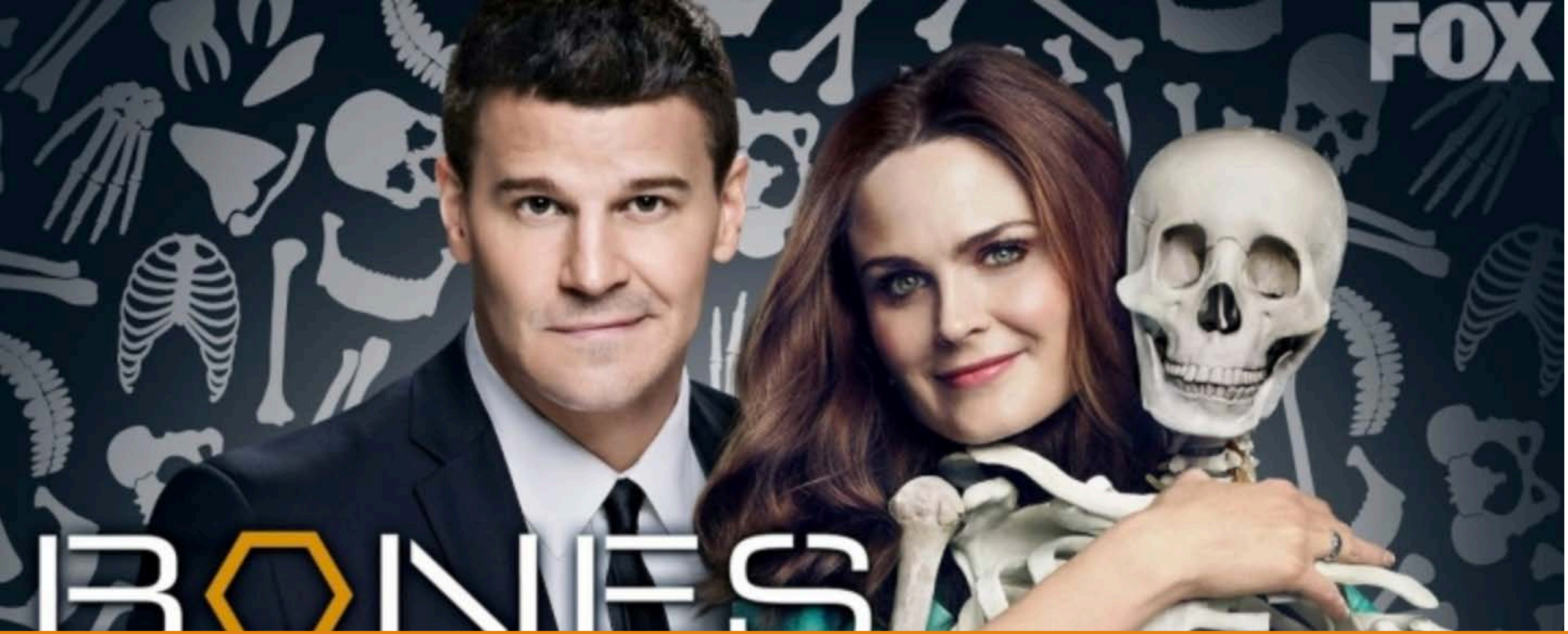
Compliance and Agility
How it can be done !

APRAJITA MATHUR

Agenda

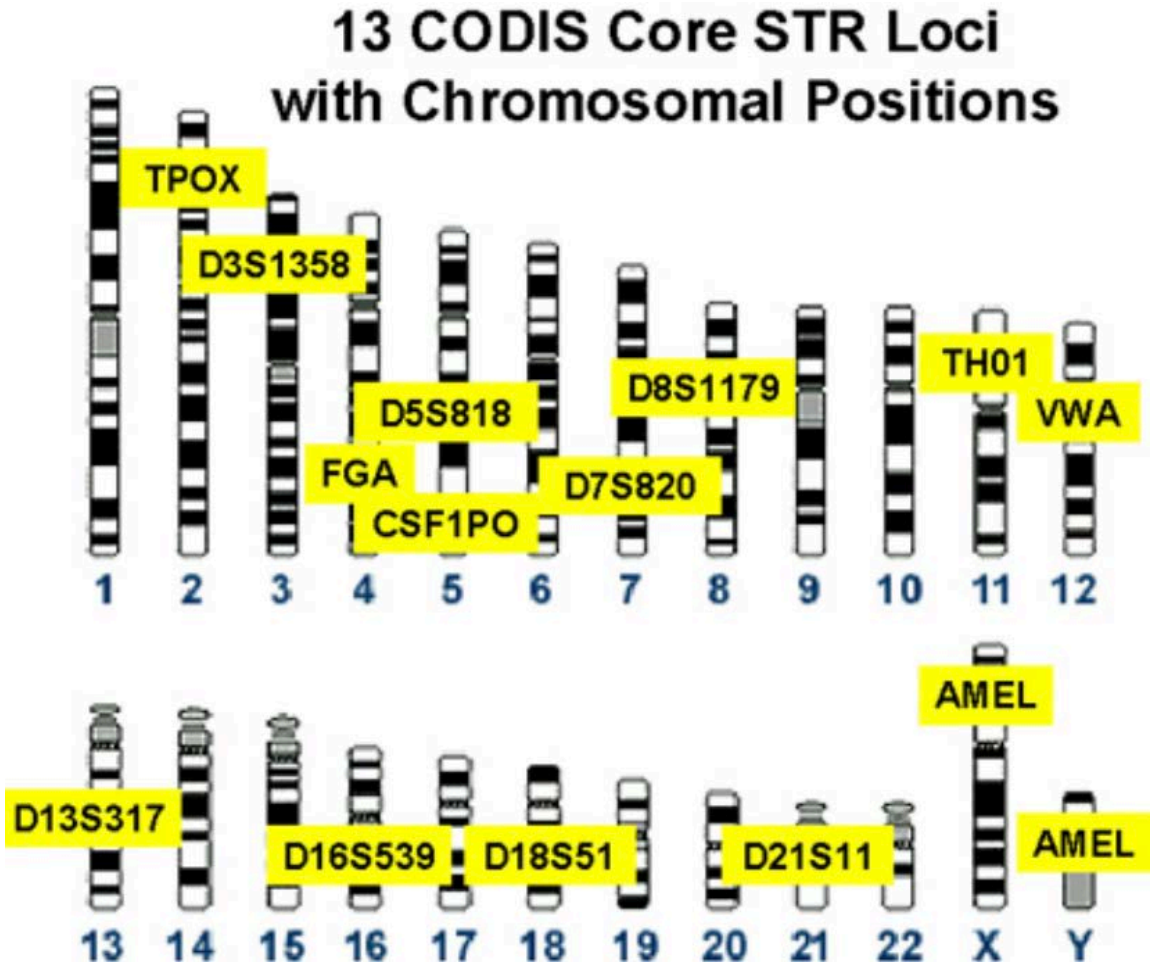
- The Project at Hand
- AgileBut
- What we uncovered
- What we improved
- What we further improved
- What worked



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.

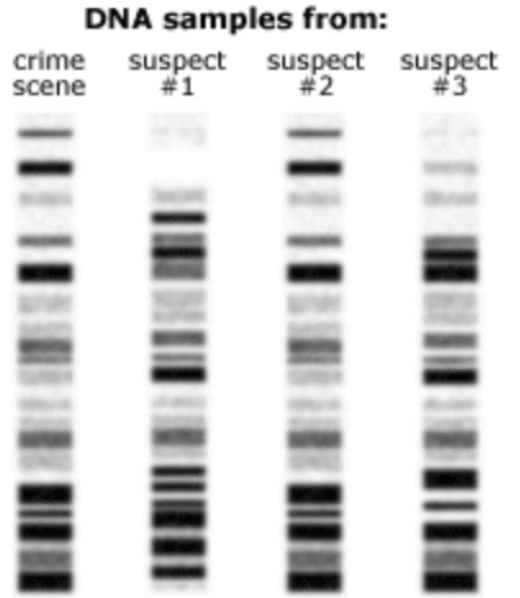


Basics Forensic Analysis

- Humans have 22 Chr pair + Sex Chr
- Locus is a Specific Location on the Chromosome
- DNA contains ATGC Nucleotides
- 13 unique Positions
- Short Tandem Repeats (STR) => (3-4 Nucleotides) n

Analyzing Data

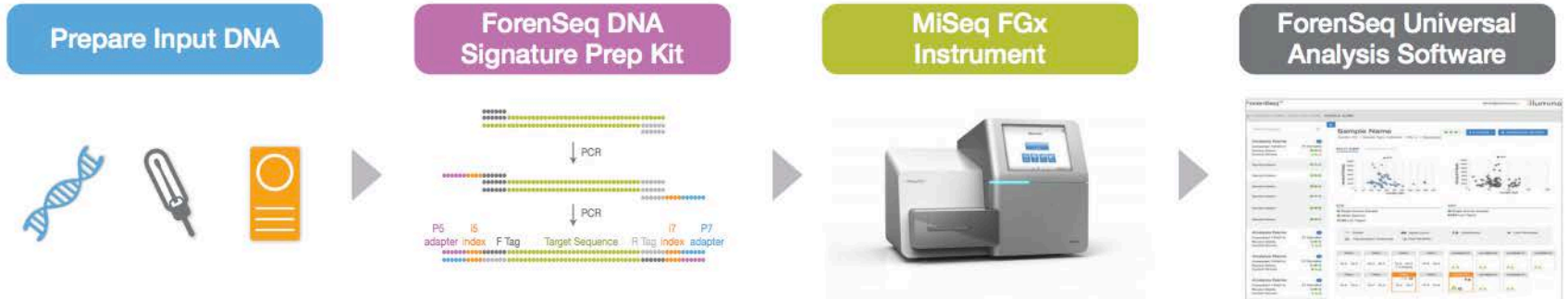
STR Locus	Evidence Sample	Suspect A	Suspect B	Suspect B's Genotype Frequency for Each STR
D3S1358	15, 17	17, 17	15, 17	0.13
vWA	15, 16	18, 19	15, 16	0.22
FGA	23, 27	21, 23	23, 27	0.31
D8S1179	12, 13	14, 15	12, 13	0.34
D21S11	28, 30	27, 30.2	28, 30	0.06
D18S51	12, 18	14, 18	12, 18	0.11
D5S818	13, 13	9, 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



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.

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

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

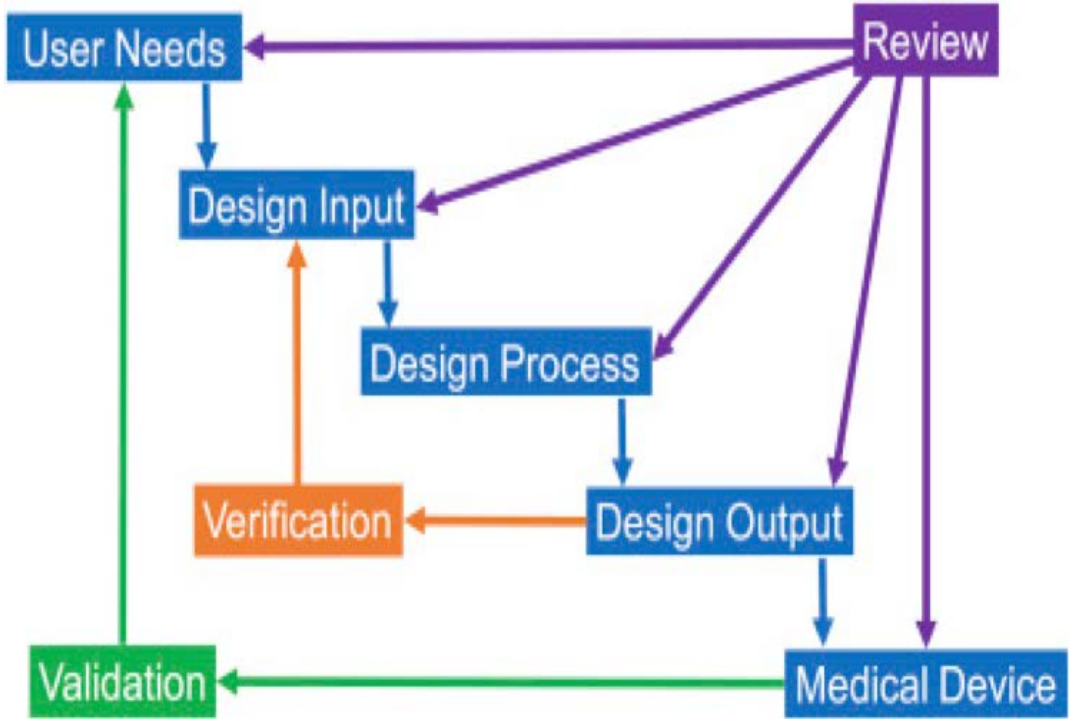
- Seamless Integration with MiSeq™ FGx
  - Kick off your run and see analysis results
- Advanced analysis
  - Automated sample comparison
  - Probability information from population statistics
  - Phenotypic and Ancestry Prediction
- User Settings: Analysis Parameters, Assay Kit Management, Custom Population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

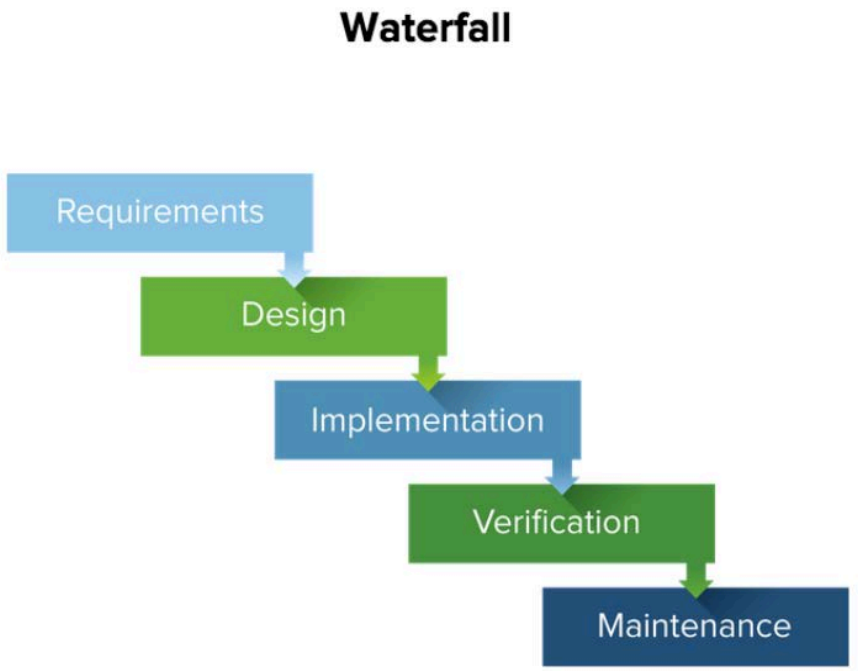
Recent News Use of NGS

- Identical Twins
- Golden State Killer


REQUIREMENTS
RULES
LAW
STANDARDS
COMPLIANCE
POLICIES
GOVERNANCE
TRANSPARENCY
REGULATIONS

Perfect Fit


User Needs
Review
Design Input
Design Process
Verification
Design Output
Validation
Medical Device

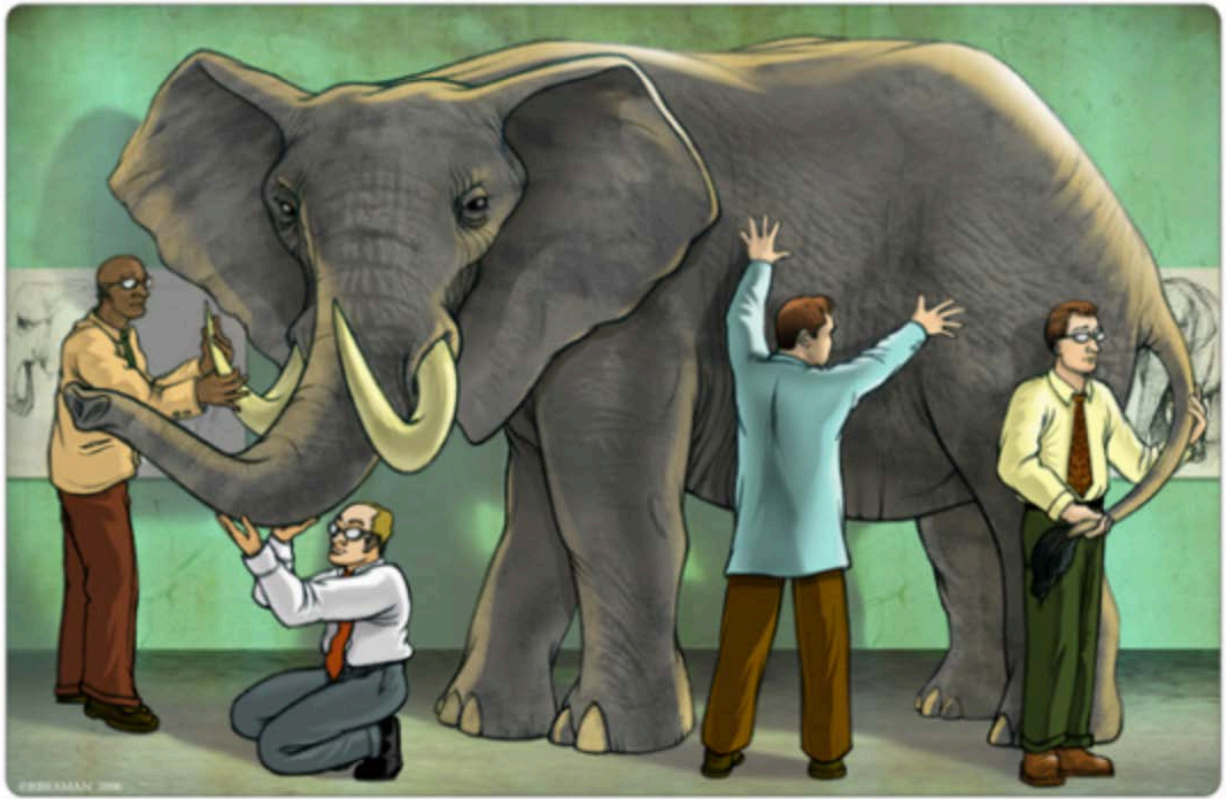

Waterfall
Requirements
Design
Implementation
Verification
Maintenance

Why Agile ?

- Allows for the Unknown *
- Allows for Integrative Development
- Allows for more frequent customer interaction
- Allows for better team collaboration
- Allows for more Visibility into Development
- Multiple Methodologies

We Are Pro-Agile !

- We have Processes
- We have Procedures
- We do Agile “Development”
- Phase Exists
- Multiple Internal Stakeholders
- My agile is the agile
- Compliance is constant



Acknowledge the Elephant

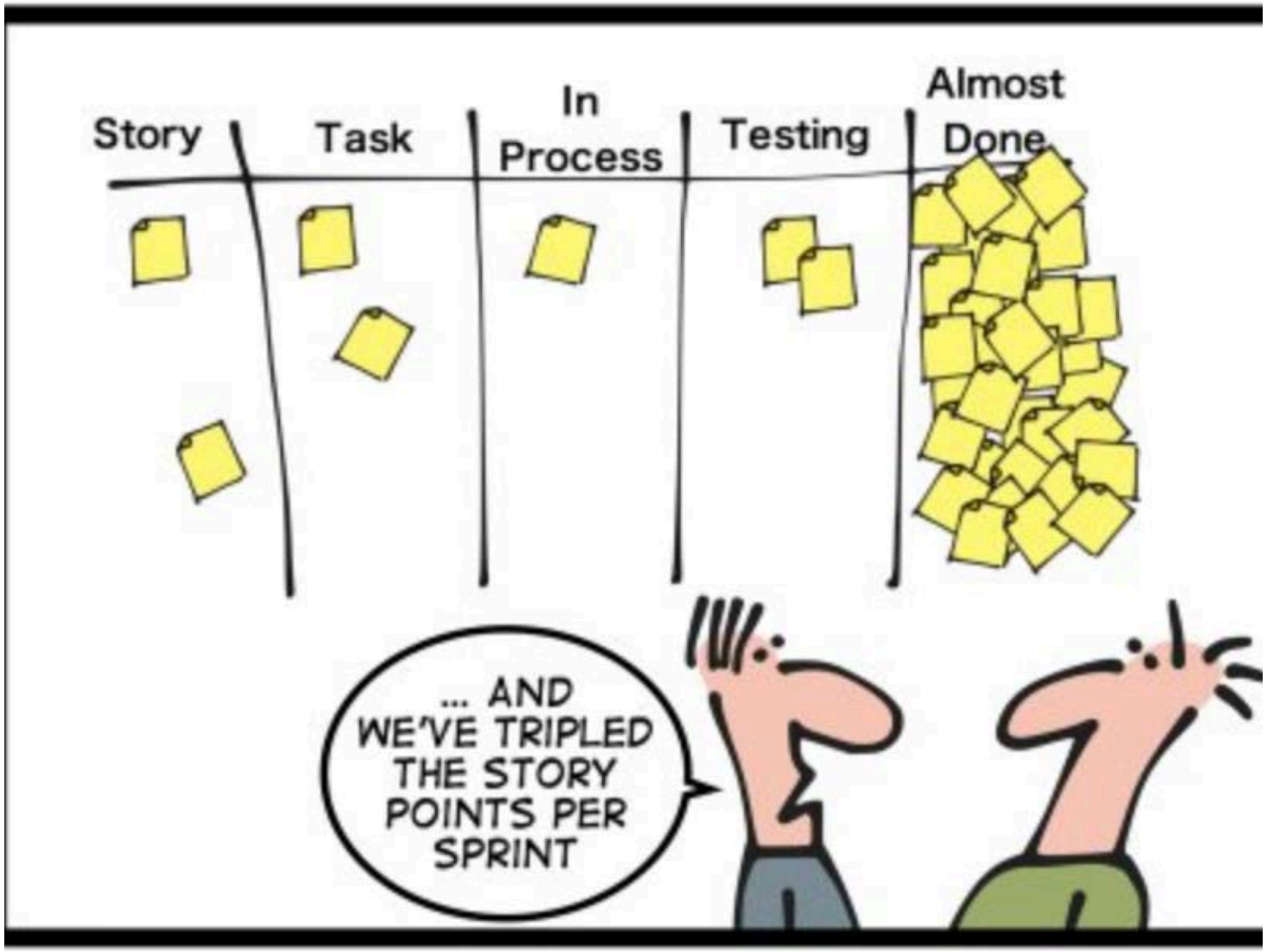
- Artifacts – Business Level
- Estimate , Track and Account
- Account for Internal Timelines
- One Point of Contact (POC)
- Scrum Master (SM)
- Product Owner (PO)
- Train and get a “Our Agile” Leveling.

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)

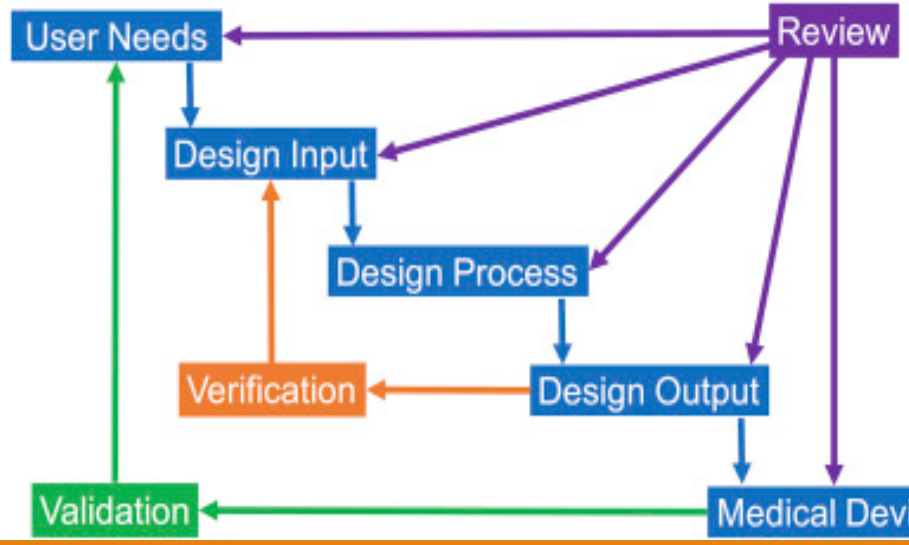
- Get the team Involved
- Automation – Build it in
  - Return on Investment (ROI)
  - Leveraged UX Workflows
  - Trace
- Manual
  - Maintenance
  - Test Steps and Modularization
- UX and UAT

Lets Talk Compliance

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

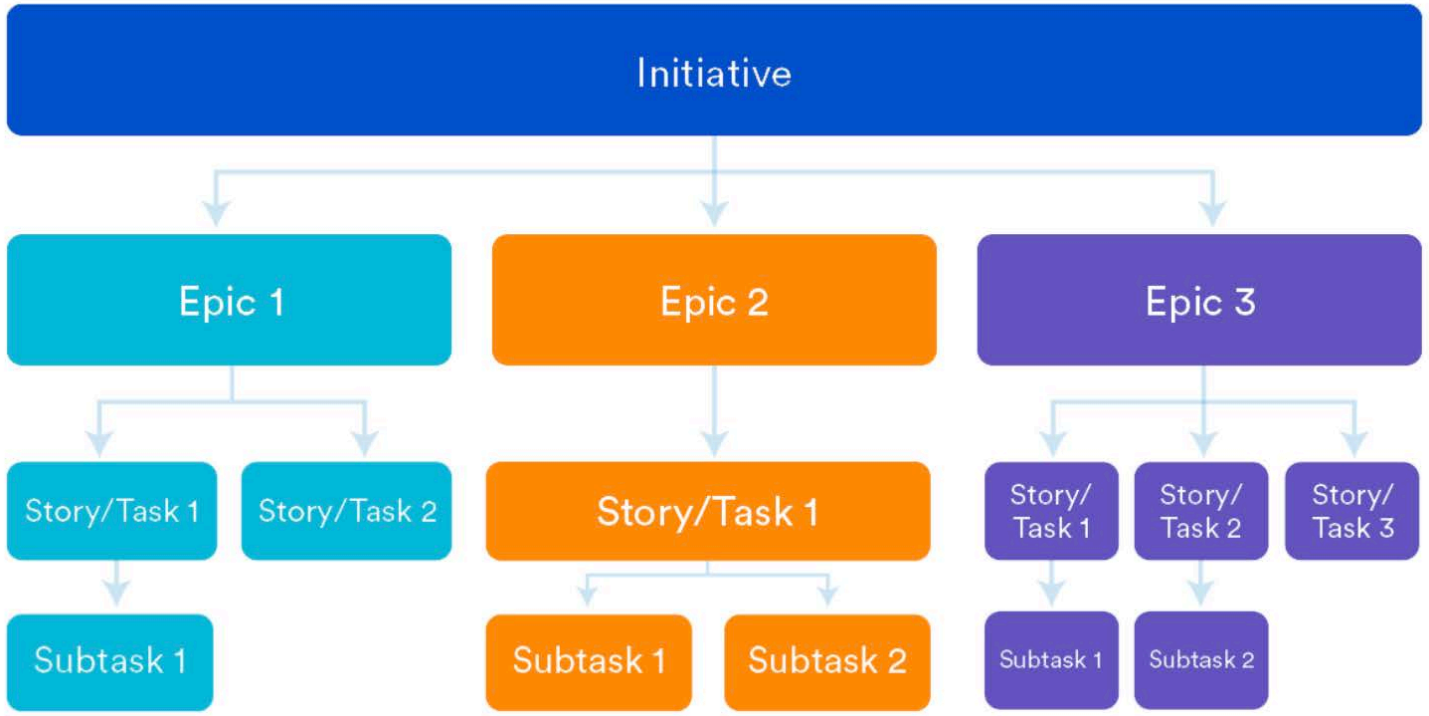
“CONCURRENT ENGINEERING : The Waterfall model’s usefulness in practice is limited. The model does apply to the development of some simpler devices. However, for more complex devices, a concurrent engineering model is more representative of the design processes in use in the ”FDA 21 CFR 820.30

- 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

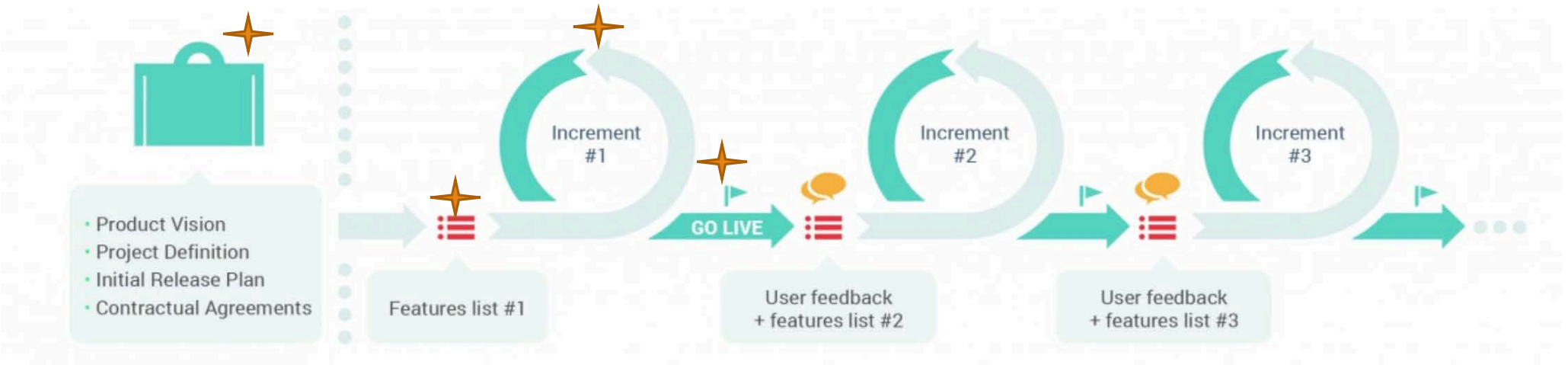
- Behavioral Changes
- Features > Epic > Stories > Tasks (Record and Trace)
- Estimations
- Planning (Review and Improve)
- Investigate (Control , SOUP /COTS)
- Demo’s (Risk , Review , Plan)
- Bug Scrub (Risk, Plan, Track)
- Document as you go

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

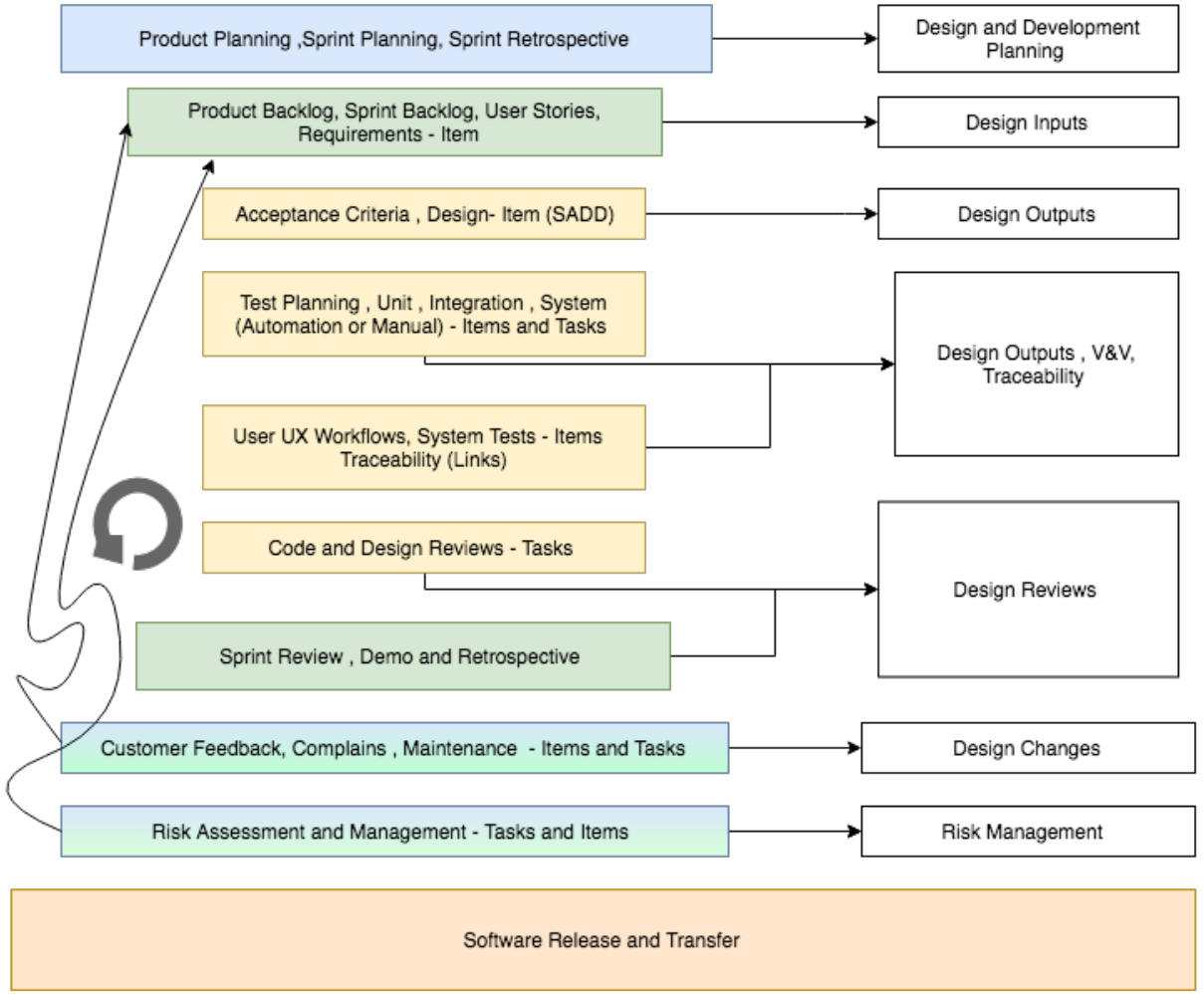
Remember the Elephant ?

- 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 !



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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

Learnings

- Define YOUR compliance
- Define YOUR Agile
- Customer at Heart ，Not a Shippable Software
- Get Testers Involved Early
- Identify Partners for TDD
- Account for ALL Team Deliverables
- Account for Business Needs

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

Questions

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References

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