Blue Stream

Bring Medical Devices to Market Faster !

UCLA CS Class Presentation

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Who Are We

Blue Stream provides software platform to reduce the time and cost to navigate regulatory pathway for launching Medical Devices.

Benefits:

- Patients get life-saving devices sooner
- Reduce the cost of health care delivery

The TurboTax for Medical Device FDA Submissions!

Experienced Team

Deep Domain Expertise (Healthcare, IT, Medical Device Regulatory and Start-Up Operations)

Soumya Mahapatra, Founder
Software and process re-engineering in Healthcare

Anna Libman, Co-founder
Regulatory Strategy Consulting for Medical Device firms

Ross Lu
Marketing Strategy, Brand and Product Management for Medical Products

Tae Macias
Seasoned CPA and CFO, Startup operations

Frank Mikel
Operations, Healthcare Technology & Facility Management

Why is it complicated ?

Regulatory search & strategy

1 Medical Device Founder

1-2 days

1 Meet with Regulatory Consultancy

1 day

2 Gather Device Information

Iterative

3-4 weeks

Regulatory Professional **5**

3 Search FDA Databases

4 Search relevant, websites, google

1-2 Weeks

6 Develop Strategy

1 day
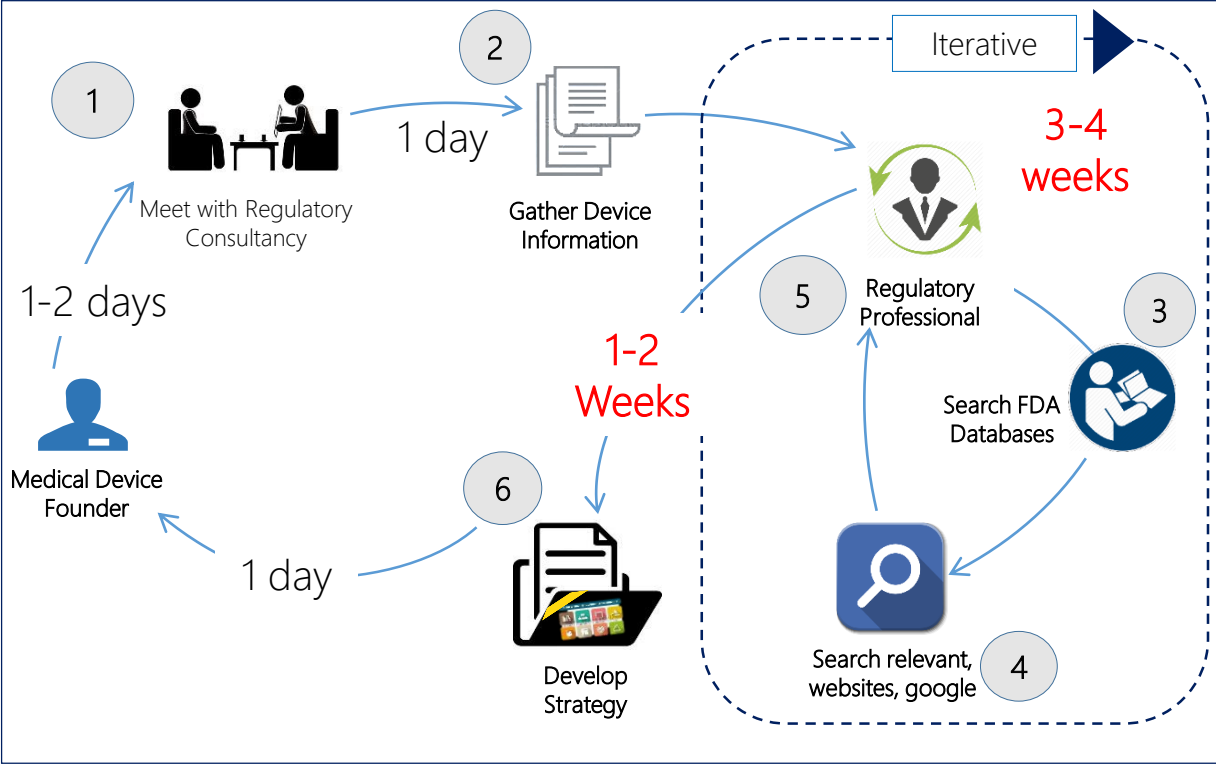
FDA Submission Management

Regulatory Professional

Standards **+**

Word Templates **+**

Protocols **+**

Regulatory guidelines **+**

Project Manager

Clinical

Engineering

Bio-comp.

R&D

Quality Assurance

⚠ **Poor Quality** ⚠ **High Turn Around Time** ⚠ **Labor-intensive** ⚠ **Steep Learning Curve** ⚠ **Siloed Teams** ⚠ **Manual Submission**
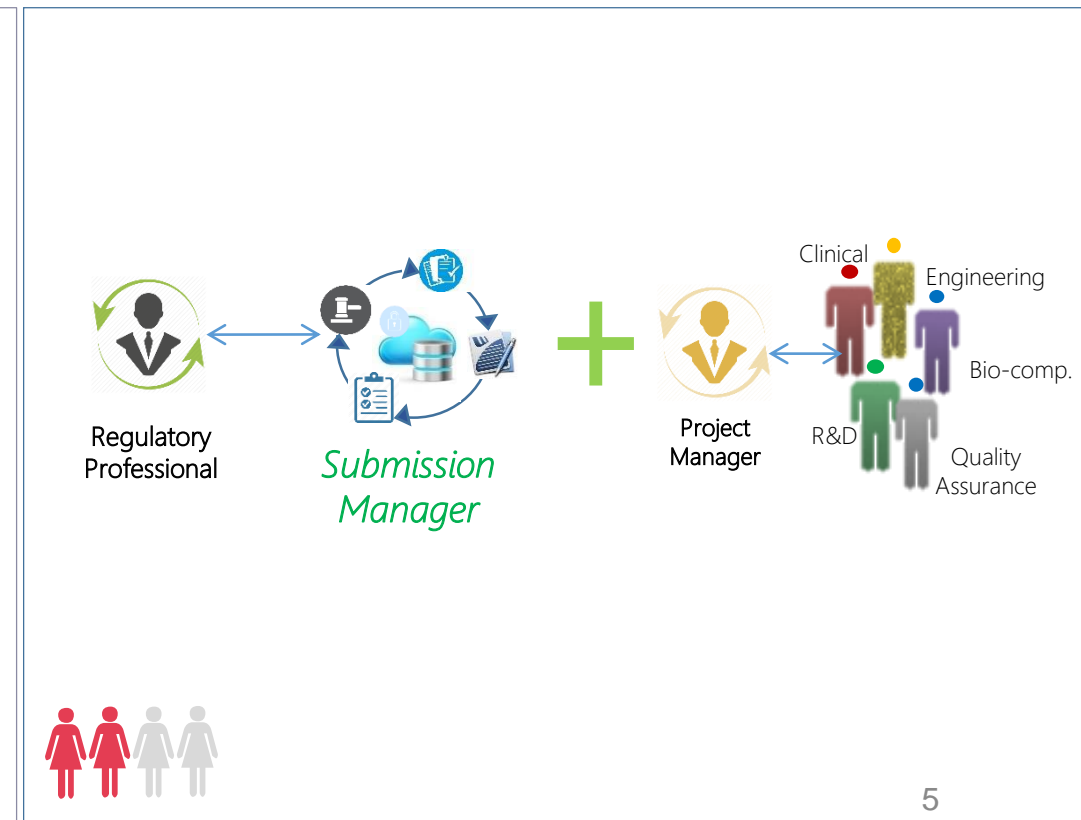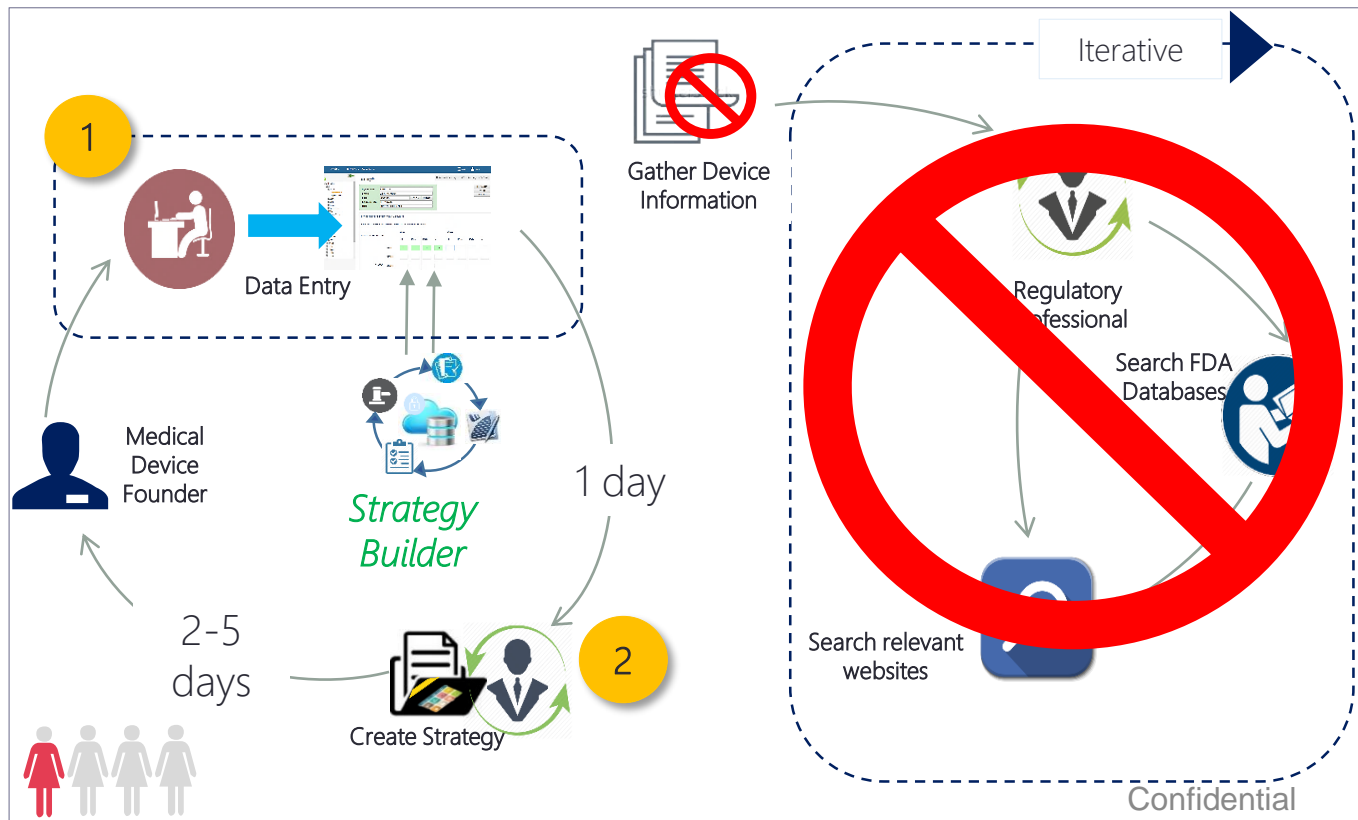
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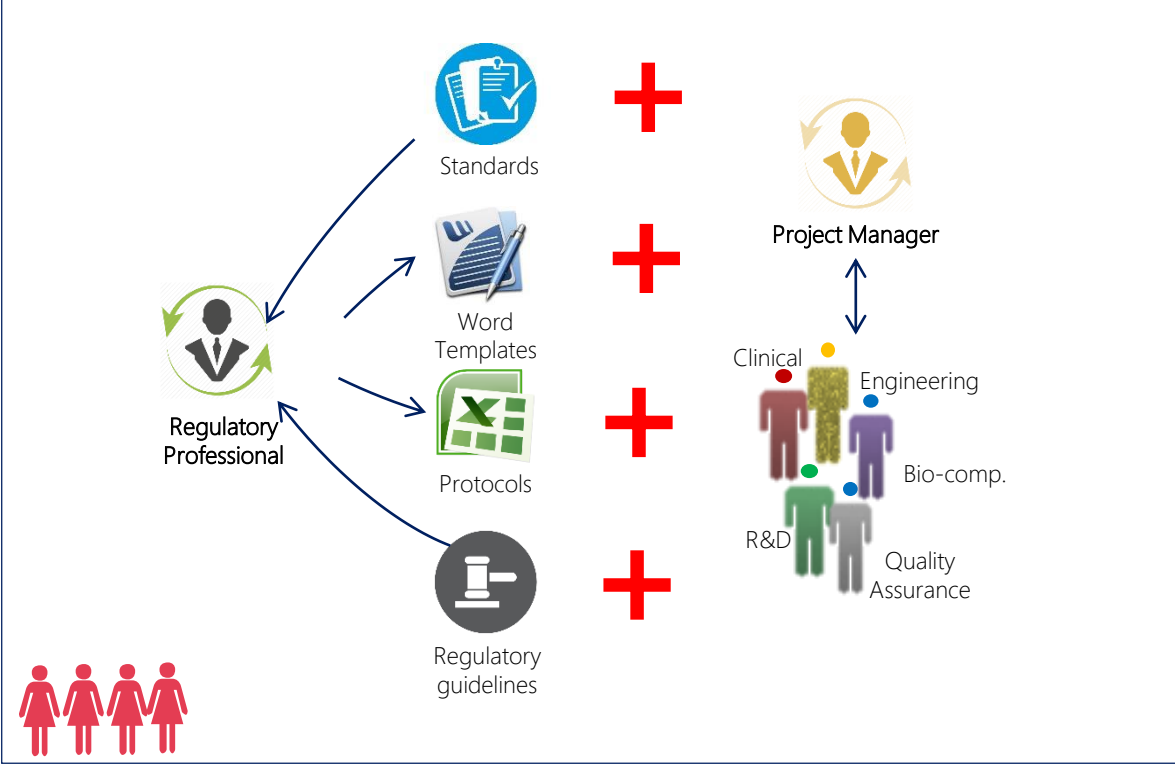
Blue Stream Software for Regulatory
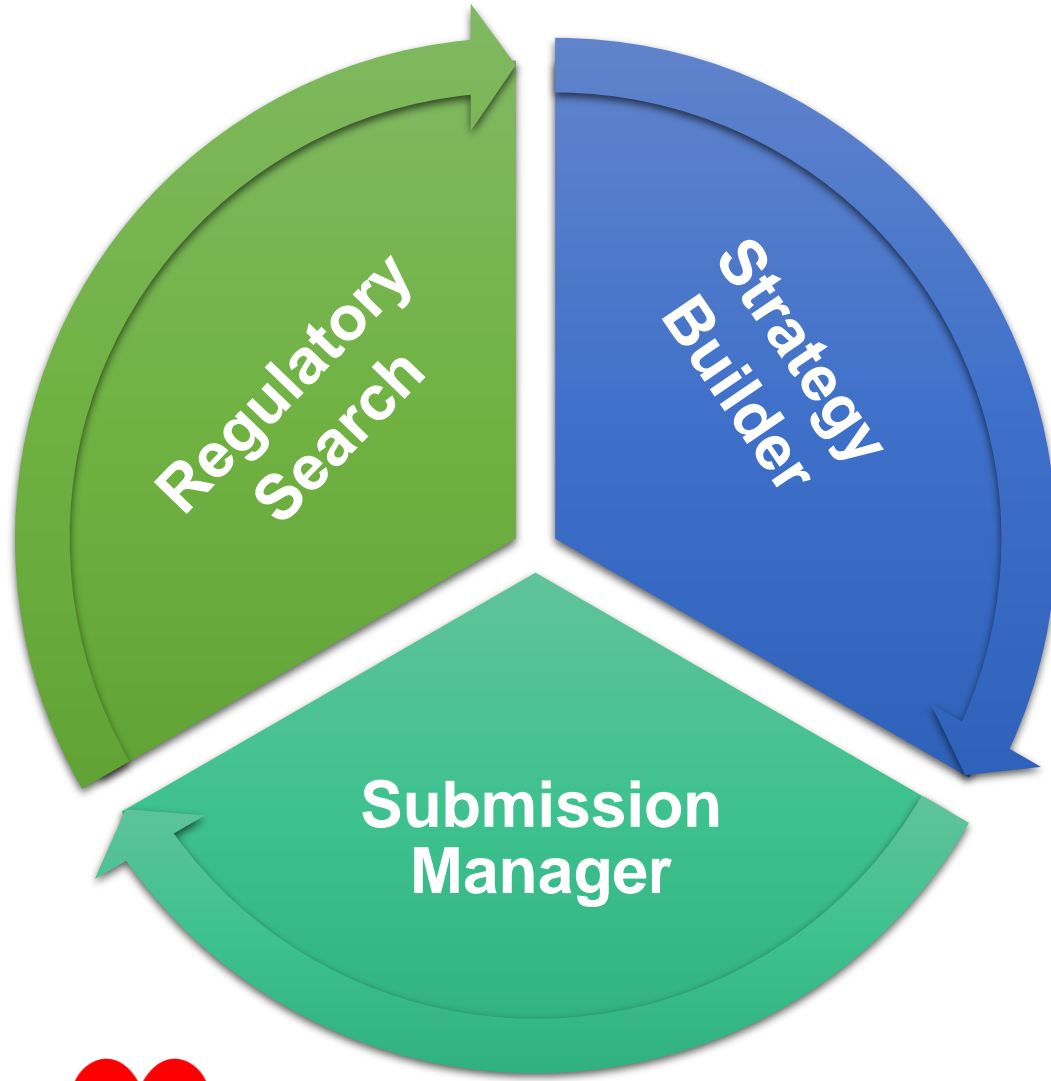
A platform that leverages advanced analytics and intuitive user design to streamline manual processes, reducing time and cost of FDA submissions

Regulatory Strategy Builder + Regulatory Submission Manager

Product Suite

Regulatory Search

Strategy Builder

Submission Manager

Regulatory Search

- Search device type, use and technology
- Competitors products, risk classification
- Device recalls and registration information

Strategy Builder

- Workflow Tool with integrated search capability
- Consistent information flow from search
- Decision making and easy-selection options
- Determine resources and time

Strategy Manager

- Collaboration tool to manage submission prep
- Custom task assignment, tracking
- Automate validation, alerts and notifications
- 360 degree view of submission progress
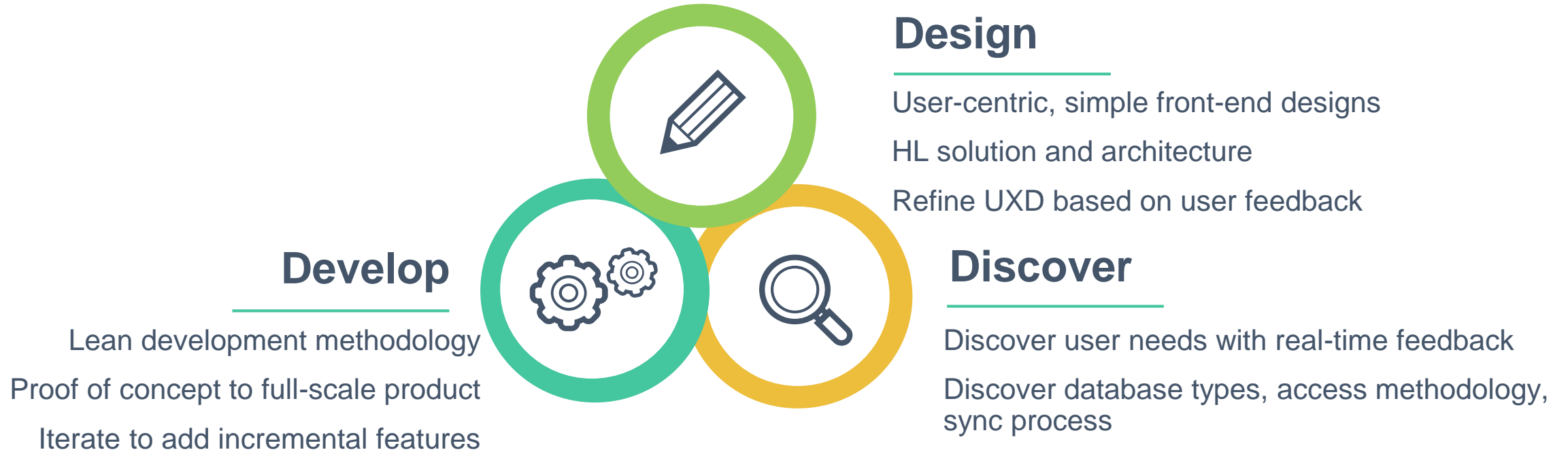- Automate 510k sections & submission

Develop easy-to adopt products that users will fall in love with!

Value to Customers

	Search	Reg. Strategy	Submission Mgt.	Overall Process
Today	2-4 Weeks	4-6 Weeks	4-6 months	Siloed
Blue Stream	✔ 5 Days	✔ 5 days	✔ 1-2 months	✔ Transparent
Value	• Predictable • Consistent	• Quicker turn around time	• Cost-Effective • Greater Control	• Collaborative • User-friendly

Product Development Principles

Design

User-centric, simple front-end designs

HL solution and architecture

Refine UXD based on user feedback

Develop

Lean development methodology

Proof of concept to full-scale product

Iterate to add incremental features

Discover

Discover user needs with real-time feedback

Discover database types, access methodology, sync process

Develop easy-to adopt products that users will fall in love with!

Project Execution Methodology

Steps

1 IMMERSE

6 PILOT & LEARN

0 ENGAGE

4 PROTOTYPE

5 ASSESS & REFLECT

2 PLAN & PREPARE

3 INNOVATE/ DESIGN
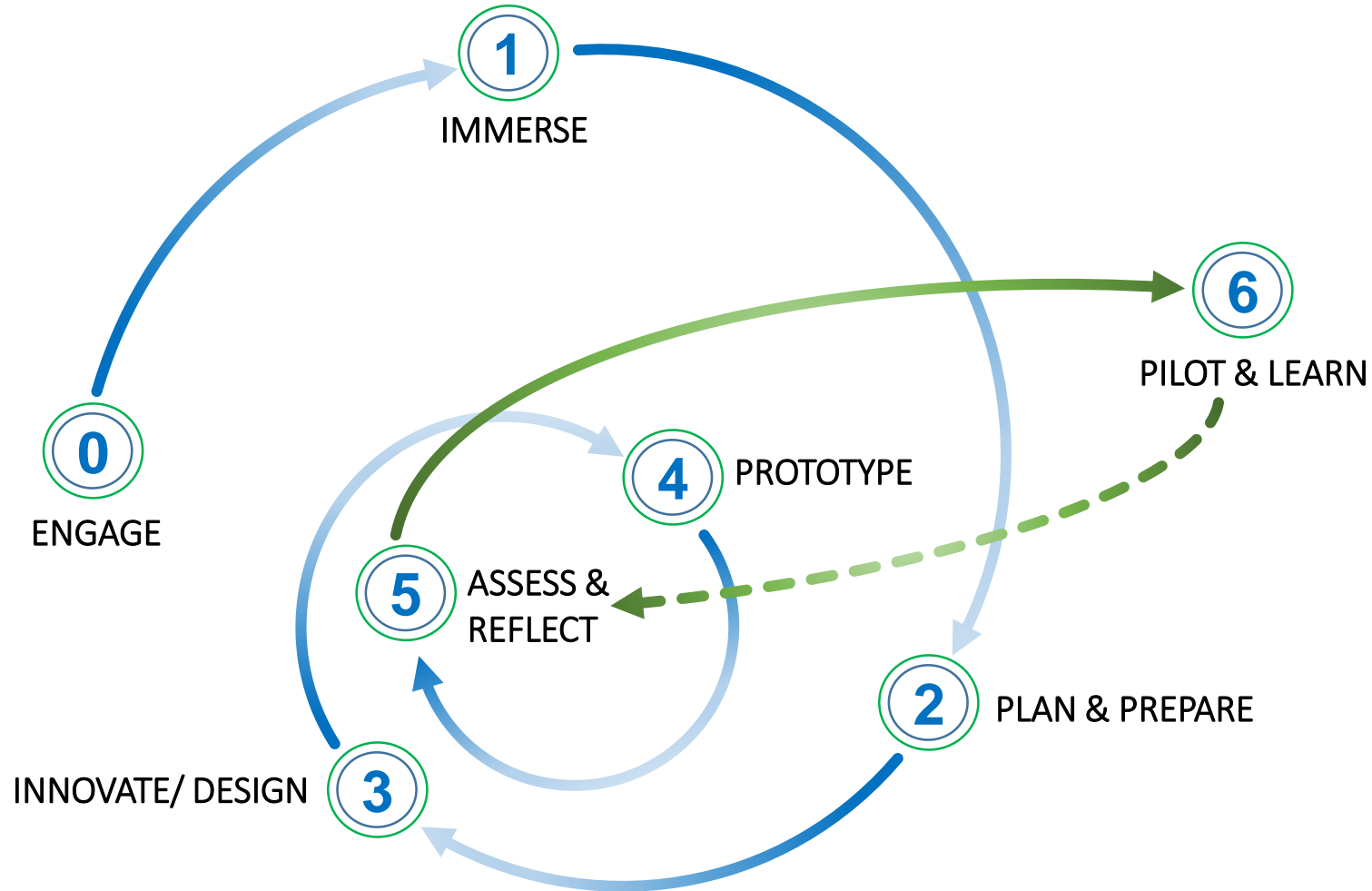
DELIVER A GREAT USER EXPERIENCE !

A Full-Stack Product Development

Components	Skill Category	Learning Category
UI screen design	UX designer	Wireframes, themes, Visuals
Front end development	Web developer	HTML, UI pages, Styles, js
Back end development	Backend dev	API development, DB- SQL, No SQL integration, Full text search
Core functionality	Natural Language processing	Full text search, parsing, relevance, ranking
Analytics/ ML (future)	Data Analyst/ Scientists	Relevance based on datasets
Databases	Database Designer	DB modelling, NO SQL schema design, integration with API and front end.

Access to Prototyping Tools and AWS for the best learning experience!

What to expect from the Project

- Solve real-world problems in healthcare in U.S.

- Gain hands-on expertise on emerging tech

- Full-scale software development lifecycle

- Real-time user feedback from primary research

Thank You