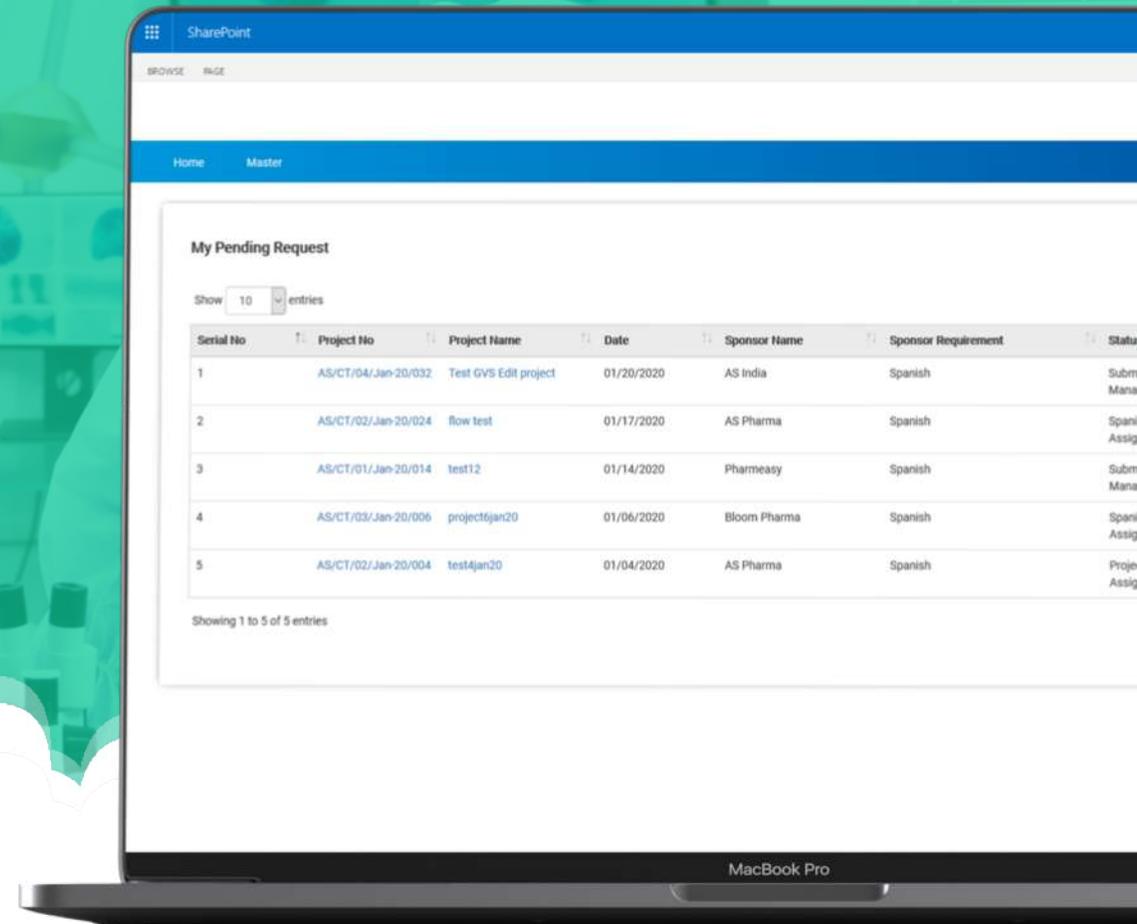




Bloom Consulting Services
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India | Singapore

Clinical Trials Protocol Approval System



Case Study



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About the client

- A leader in clinical research in Latin American region
- Our client is a comprehensive clinical and analytical solutions provider focused of research, helping pharmaceutical companies in their quest for better and safer medicines
- Founded in 2011 and headquartered in Monterrey, Nuevo León, Mexico, they have grown to be 200 strong
- Their operate and target the North and Latin America



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Services

Problems due to old process

- Client was using a file-server to host their documents
- Approval process was carried out on emails
- Manual version management
- Difficult to use due to collaboration issues, document change conflicts were common
- The protocol manager was supposed to manually track, review changes and notify approvers regarding pending approval

The client wanted a digital approval system in which various employees from different business units and countries can easily create approval requests. They specially wanted to have complete version control on various documents being created as a part of protocol followup.

Solution Objectives

- Client wanted a highly secure system of their own to maintain their confidential data
- System should be secure enough to handle confidential data
- Streamlined approval process, with ease of use and automation
- Tracking and versioning of document throughout and after the approval process



Solution Details

- Whole approval process is covered by system, so that users don't have to rely on emails or any third party tool
- Easy tracking and version management, let the users access any version of any document whenever needed, without worrying about overwriting or storing multiple backups of the same file, hence eliminated redundancy
- System is designed to make the users transition from their old method to the new system with less efforts. Even though they weren't using a tool earlier, they need minimal training to be comfortably using the system



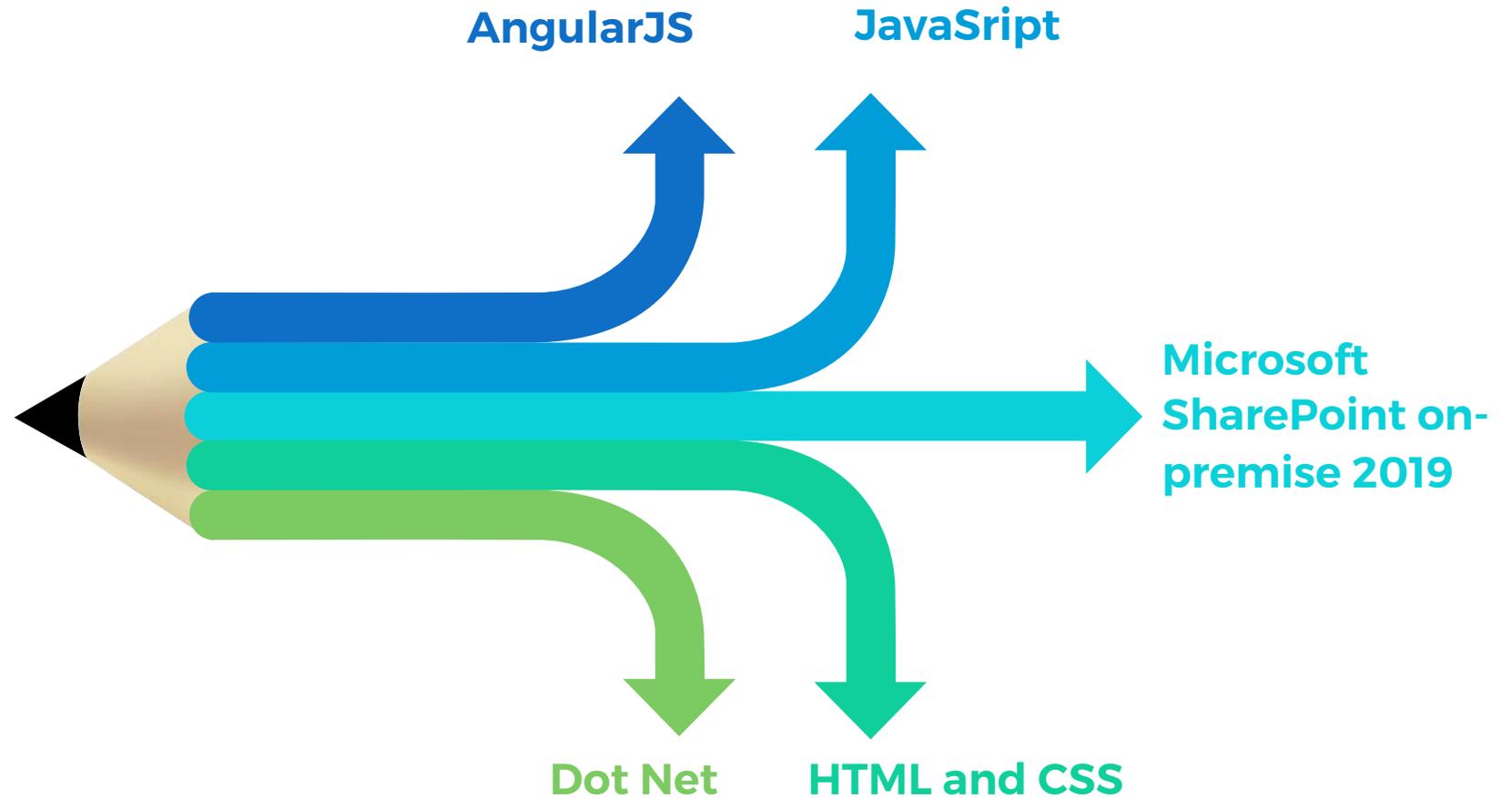


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Technology Stack

We used SCRUM to manage the project and deliver value iteratively

Technology Stack





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Bloom developed the entire project from start and client wanted to retain the default UI of Microsoft SharePoint while concentrating more on process improvement and quick deployment.

There was a challenge to to work with global team of client and we used Hub and Spoke engagement model to implement the project.

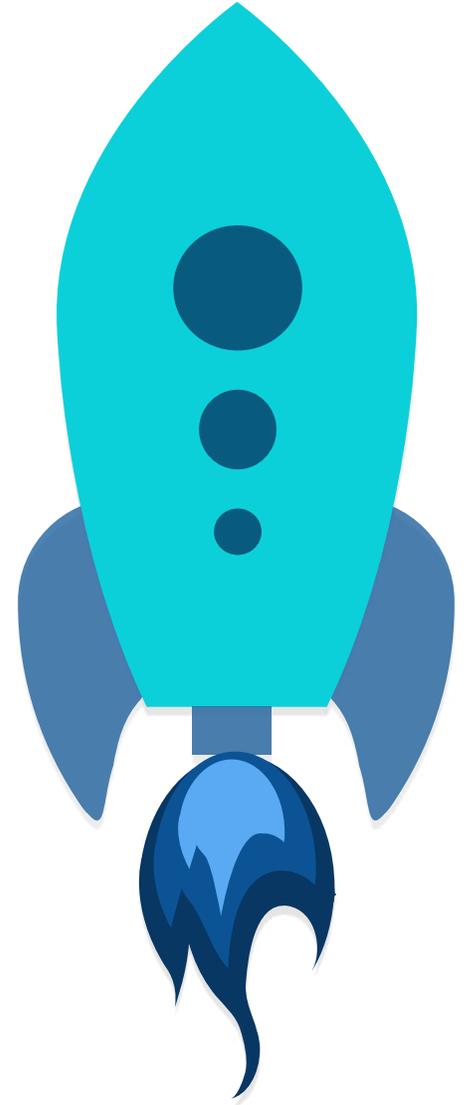
The team

- Product Owner
- Scrum Master
- SharePoint Architect
- Lead SharePoint Developer
- Web Developer
- Business Analyst
- QA engineer



Business Impact

- Complete visibility into the status of any approval request
- Custom routing and workflow based on the department or organization's needs
- Set automated alerts and reminders for any part of the process
- Sequential or parallel routing
- Single or group approvals
- Automatically maintain a complete audit trail of all activity and communication



SCREENSHOTS



Bloom Consulting Services

My Pending Request

Serial No	Project No	Project Name	Date	Sponsor Name
1	AS/CT/04/Jan-20/032	Test GVS Edit project	01/20/2020	AS India
2	AS/CT/02/Jan-20/024	flow test	01/17/2020	AS Pharma
3	AS/CT/01/Jan-20/014	test12	01/14/2020	Pharmeasy
4	AS/CT/03/Jan-20/006	project6jan20	01/06/2020	Bloom Pharma
5	AS/CT/02/Jan-20/004	test4jan20	01/04/2020	AS Pharma

Showing 1 to 5 of 5 entries

Create New Project

Project Name:

Sponsor Type:

Primary Language:

Applicable regulatory:

Project type:

Scope Of The Study:

- Clinical study (BA/BE)
- Test B
- Regulatory process

Investigational Products Information:

- Reference Product
- Test Product
- Additional (Test 2 or Reference 2)

Project Name:

Sponsor Name:

Molecule:

Secondary regulatory:

Sponsor Requirement:

Date:

Spanish English

Statistical analysis

Informative

Bioanalysis

BE exemption

SCREENSHOTS



Bloom Consulting Services

Completed Request

Show 10 entries

Serial No	Project No	Project Name	Date	Sponsor
1	AS/CT/02/Jan-20/026	Test GVS 11 - English	01/17/2020	AS Pharma
2	AS/CT/AD/Jan-20/025	Demo 17-01-2020	01/17/2020	Socorro M
3	AS/CT/01/Jan-20/016	Test GVS 6	01/14/2020	Pharmea
4	AS/CT/01/Jan-20/008	Project test running	01/13/2020	Pharmea
5	AS/CT/01/Jan-20/003	test	01/03/2020	Pharmea
6	AS/CT/01/Dec-19/031	protocol3012	12/30/2019	Pharmea
7	AS/CT/AD/Dec-19/021	Demo AS Project	12/20/2019	Socorro M

Showing 1 to 7 of 7 entries

Project View

Project Name : project6jan20

Sponsor Type : National

Primary Language : Spanish,

Applicable regulatory : ABC

Project type : Bioequivalence

Scope Of The Study : yes

Clinical study (BA/BE) : no

Statistical analysis : yes

BE exemption : no

Regulatory process : no

Date : 01/06/2020

Sponsor Name : Bloom Pharma

Molecule : sample

Secondary regulatory : COFEPRIS, ABC

Sponsor Requirement : Spanish

Bioanalysis : no

Test B : yes

Informative : no



About Bloom

We are a Singapore and India based software development company, specialised in developing web applications and mobile apps for other companies on iOS, Android and Windows Phone, as well as being experts in social applications and API integrations. We are a team of 50+ in-house developers, designers and advisors all passionate about applications.



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