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Project Management in SharePoint - utilities empowering process in clinical domain

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ABSTRACT

Clinical domain is an extraordinary cuisine which involves several stakeholders, partners, tools and processes. Project management in clinical domain involves sponsors, service providers and any other third-party stakeholders such as laboratories/research labs etc. Having a centralized mechanism which involves easier navigation, tool authentication, audit trail, e-verification and approval process will ease the process.

There are several tools in the market which individually cater to the needs of our requirements. However, this paper would share information regarding how an employee lifecycle management system was built on SharePoint, the workflows involved in doing so and meeting the requirements of 21 CFR Part 11 and ICH GCP documentation guidelines.

Recruitment process - raising indents, interview schedule, feedback management, review and approval; HR process - document repository, employee information log, leave management system; Asset management - asset database, disbursement, review and approvals; Project management - task assignment, project status, escalations and commendations, timeline management, contact information; Exit process - approvals, timelines and feedback management.

The paper would include screenshots and code-bits of the workflows involved in building a robust life-cycle management system. The focus would be on project management involving team information, contact log, task assignment and status management, customer feedback management, timesheet portal etc.

This will showcase end-to-end process management using Microsoft SharePoint tool and its integration with the organization's eco-system.

INTRODUCTION

Protocol is the bible in the era of clinical trials and a well-structured protocol may answer clinical questions, but it requires better handling at the project level to ensure success. Projects and process are the essence of any business. Efficient way of working and meeting organization goals effectively would require more than just capable workforce giving their best. Clinical domain today rides on cost, quality and timeline – there is immense pressure on the industry to deliver extremely top-notch products to the market in the most cost-effective manner within a said timeline ensuring the business is profitable too. According to a survey, it's being inferred that for every $1 billion invested in the project, more than $122 million goes in waste due to poor project handling/performance – that's a whopping 12 percent. Let's corelate this to clinical drug industry. Approximate drug development cost would hover around $250 million; and twelve percent waste would amount to $30 million. Best project management practice can be a lifeline here ensuring effective outcome. It's also observed that in organizations which have a culture of effective project management – around 71% of the projects meet original goals and it's sad to know that only around 38% of the organizations make it a priority to create a culture of effective project management.

CLINICAL PROJECT

A project can be defined as "a temporary endeavor undertaken to create a unique product, service or result." – as defined in the PMBOK guide. Each project is presumed to have a beginning or an end. The end is reached when the project's objectives have been achieved or when the project is terminated because its objectives will not or cannot be met. In our domain, every clinical trial is a project. Applying

project management as a disciplined practice, a clinical trial as a project begins with the initiation of protocol development and normally ends with report submission to regulatory bodies, post market analysis. These trials comprise many components, such as study start-up, recruitment, labs, investigational product, data, materials, site management, statistical programming. These are considered sub-projects within the clinical trial project, and they need to be fully managed with the same project management disciplines.

Project evaluation is the key in the industry. And clinical industry is known for rigid compliance requirements including ICH GCP guidelines, HIPAA, 21 CFR Part 11 compliance etc. Observing and checking datapoints through the lifecycle of a project helps the sponsor make informed decision about the status of the project and analyze risks involved and mitigate them in advance.

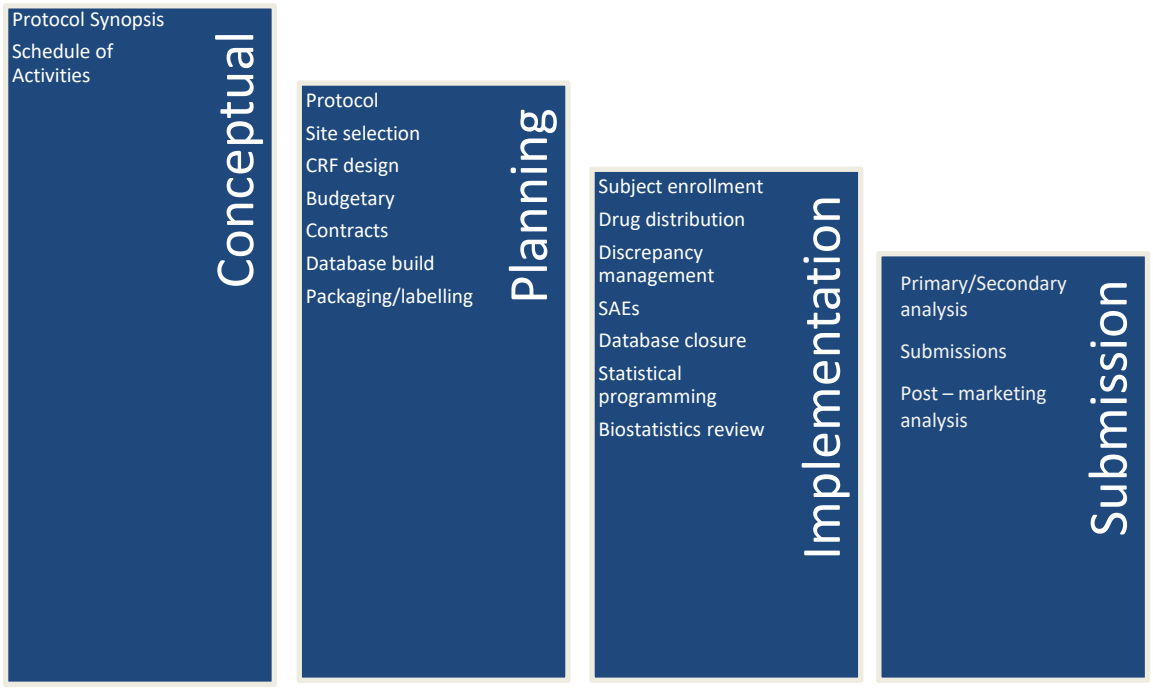


Figure 1. Process in nutshell

The Five Steps of Project Management:

Initiating: Define vision and initial project scope, identify stakeholders.

Planning: Establish and define total scope of the project, build timelines, establish risks, milestones, stakeholder management, and budgets. Planning is a significant portion of the project.

Execution: Acquire, develop, and manage the teams, perform quality assurance, manage communications, engage stakeholders, and attain goals.

Monitoring and controlling: Adjust along the way and determine if the project needs to be terminated, adjusted, or continued. Control project work, scope, schedule, cost, communications, and risk.

Closing: End the project using a formalized process.

PROJECT MANAGEMENT TOOLS

Project management process also gave birth to several software tools which would enhance the effectiveness of managing projects.

In this paper, the focus is on Microsoft SharePoint. Microsoft products – best know being the Office package – word, excel, PowerPoint has evolved too and today has many weapons in its armory – one of them being the SharePoint. SharePoint as a tool provides flexibility with two levels of design:

a. Basic design and workflow creation
    a. This involves activities such as form design; workflow creation and linking forms too with inbuilt programming interface.
b. Complex design and workflow
    a. This involves .NET programming along with VB knowledge.

Attributes of any project management tool in our domain:

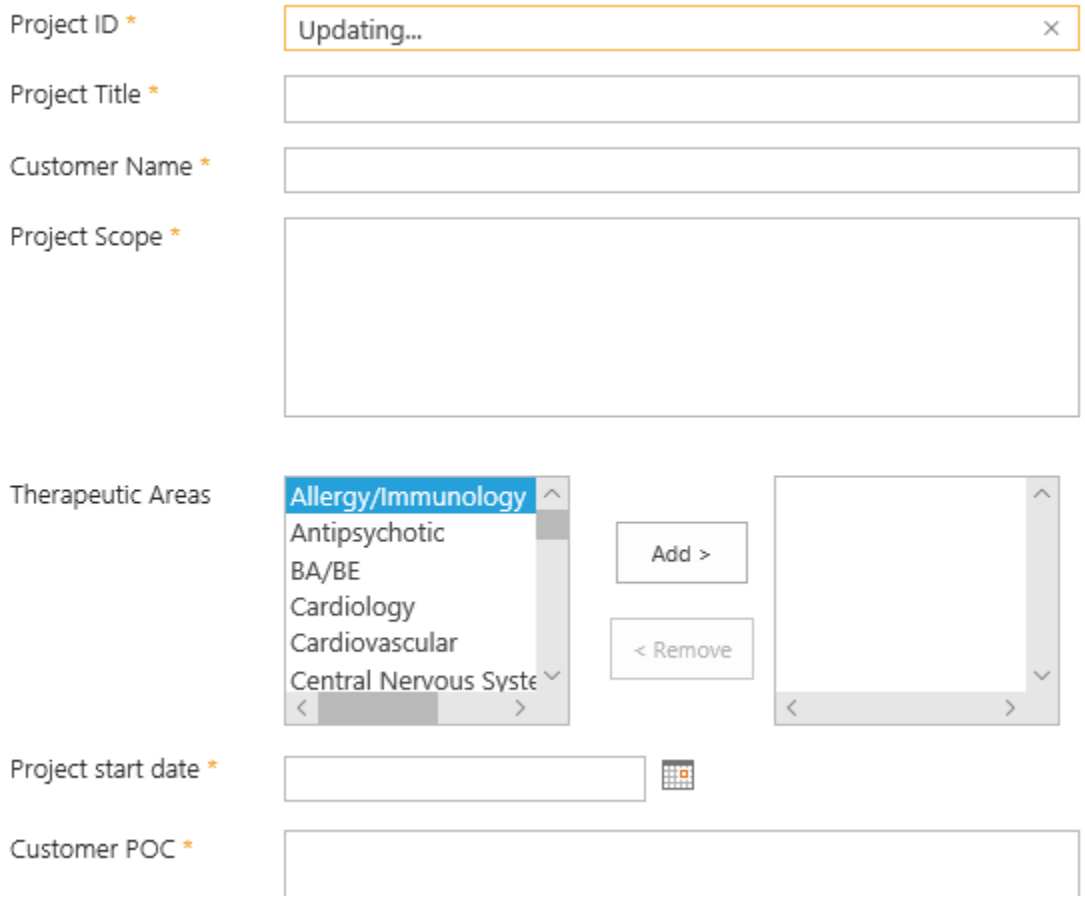
1. User friendly
2. Entire project management lifecycle
3. Scalability
4. Data retention and interactive interface
5. Data integrity
6. Data Security and compliance
7. Data availability

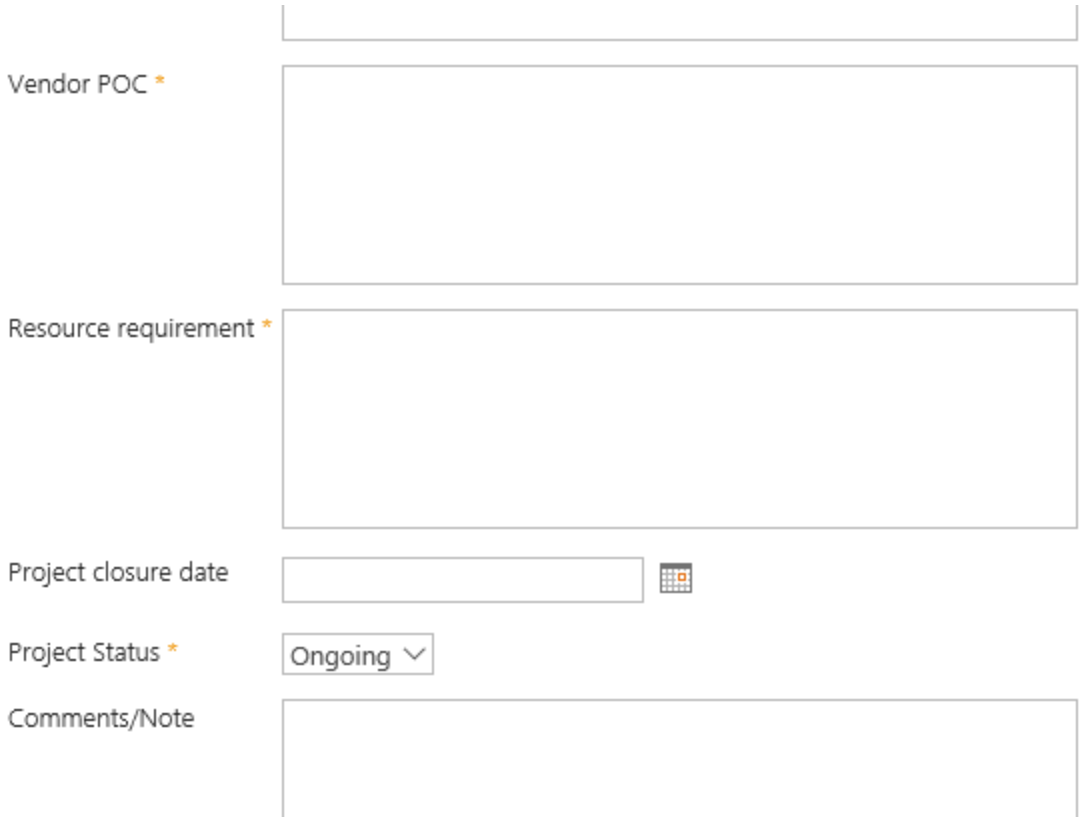
MANAGING PROJECTS UTILISING SHAREPOINT

SharePoint provides an interactive platform to develop an effective project management tool. Utilizing SharePoint, the project management interface was designed as in the screenshot below:

PROJECT INITIATION

The project initiation window would capture information related to the project/protocol – including – Project ID (this could be organization specific nomenclature which could be either manually entered or programmed to follow a naming convention); Title of the project/protocol; Customer name – based on the organization/project's need – it could be the complete name of the customer or code name; Scope of the project; Information related to therapeutic area; project start and end date; Customer and Vendor point of contact – contact information related to the respective stakeholders; resource status – resource requirements;

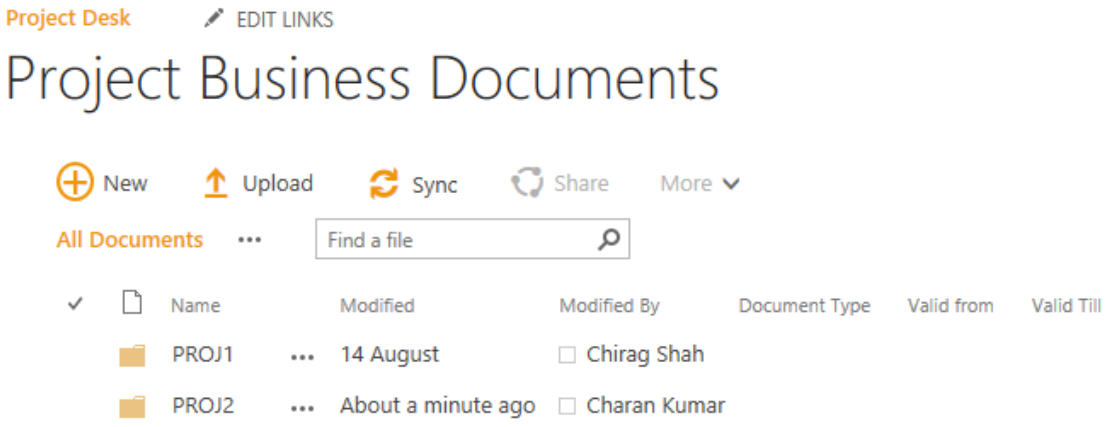




Display 1. Project Initiation Interface

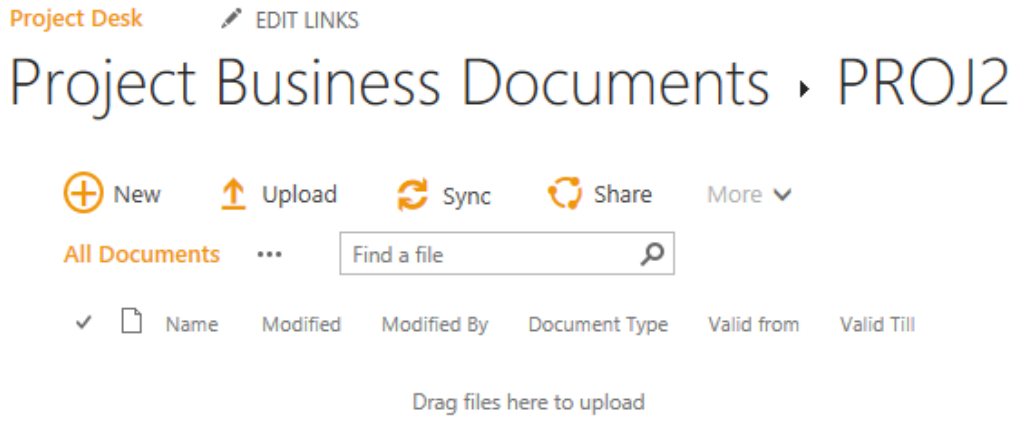
PROJECT BUSINESS DOCUMENTS

The Project Business Documents window would be a repository to store necessary documents such as contract agreements, vendor documentations etc. The folders are customizable and audit trial will be visible here.



Display 2. Project Business Documentation interface

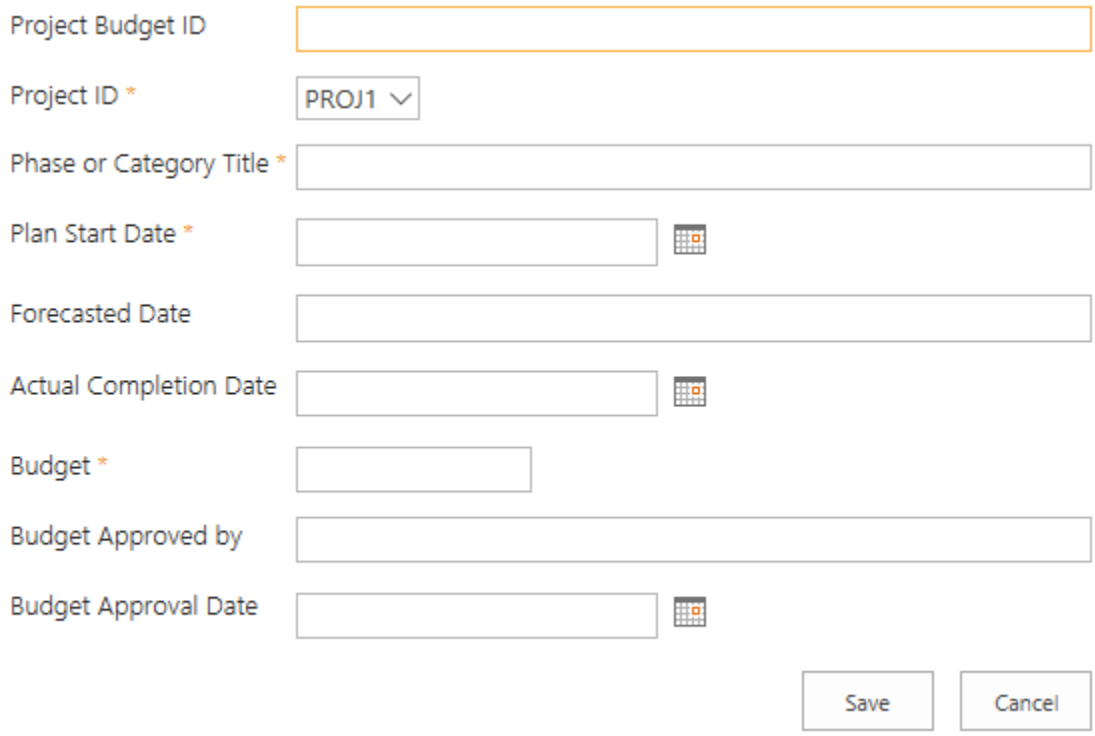
Several fields can be added including – type of document, it's validity etc. Drag and drop feature is available here.



Display 3. Folder view

PROJECT BUDGET FOLDER

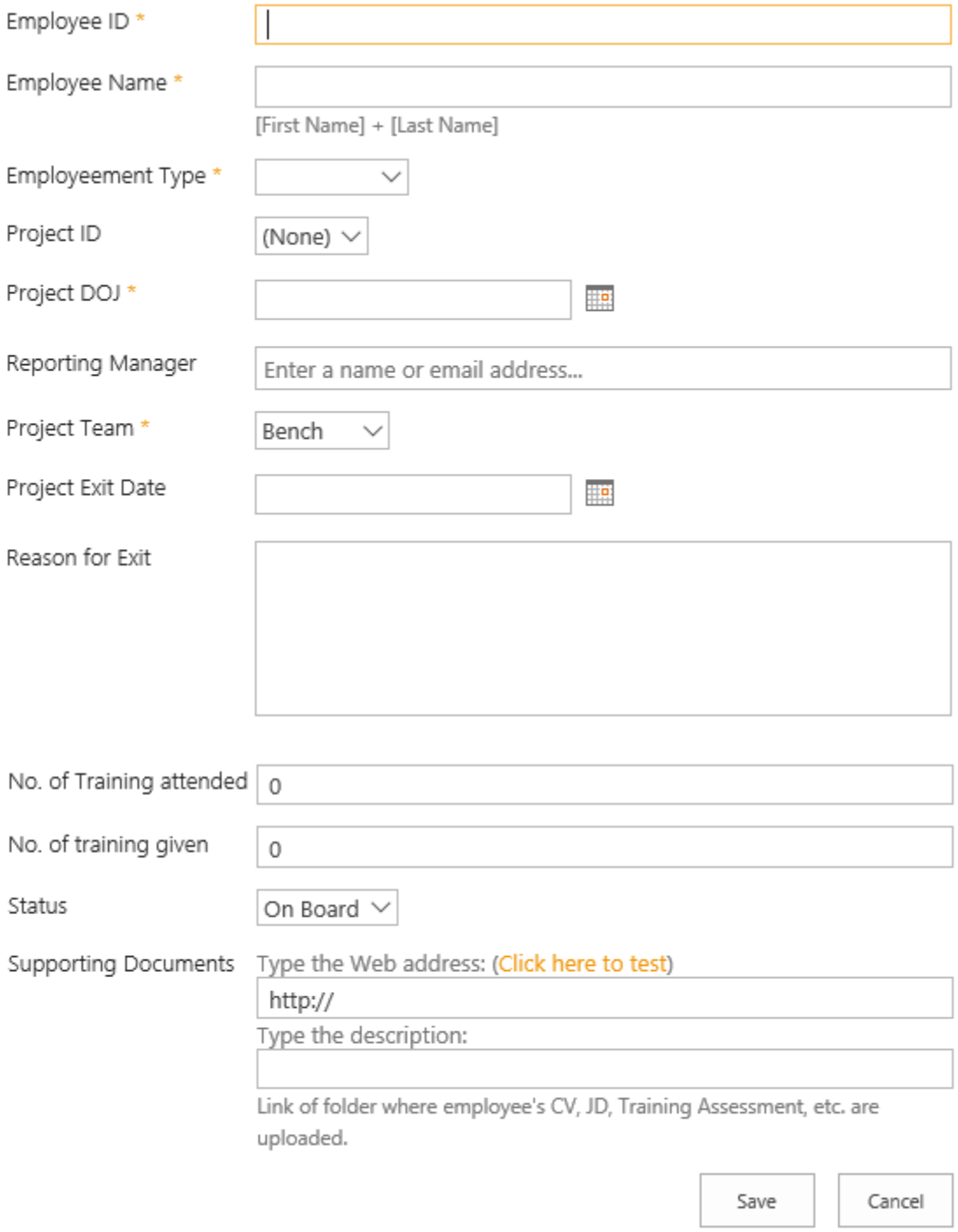
This folder has an interactive place holder to capture project budget related information including but not limited to the fields shown below:



Display 4. Project Budget interface

PROJECT TEAM

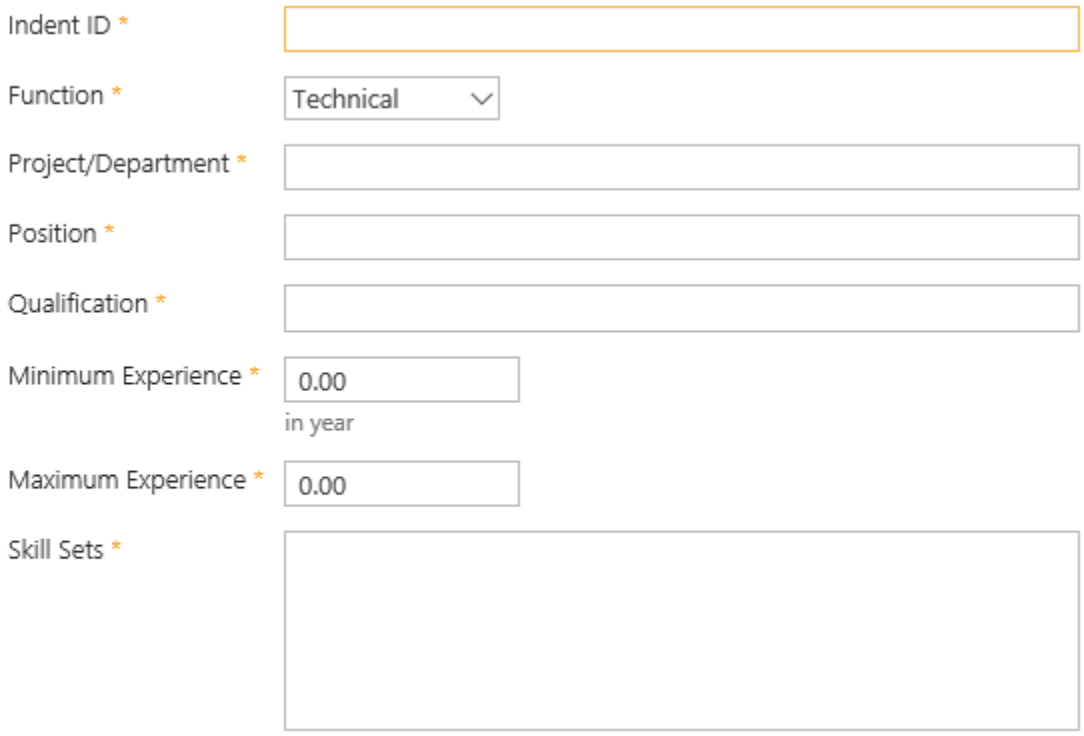
This window captures information related to the project team member(s). The limit to team members can be defined and recorded. Metadata related to project team could include – employee ID, name, type of employment, Project ID, Date of joining the project, his/her reporting manager, information regarding certain prerequisites in our domain such as CV of the employee, training records could be part of the team window. Project exit information is also captured in this form.

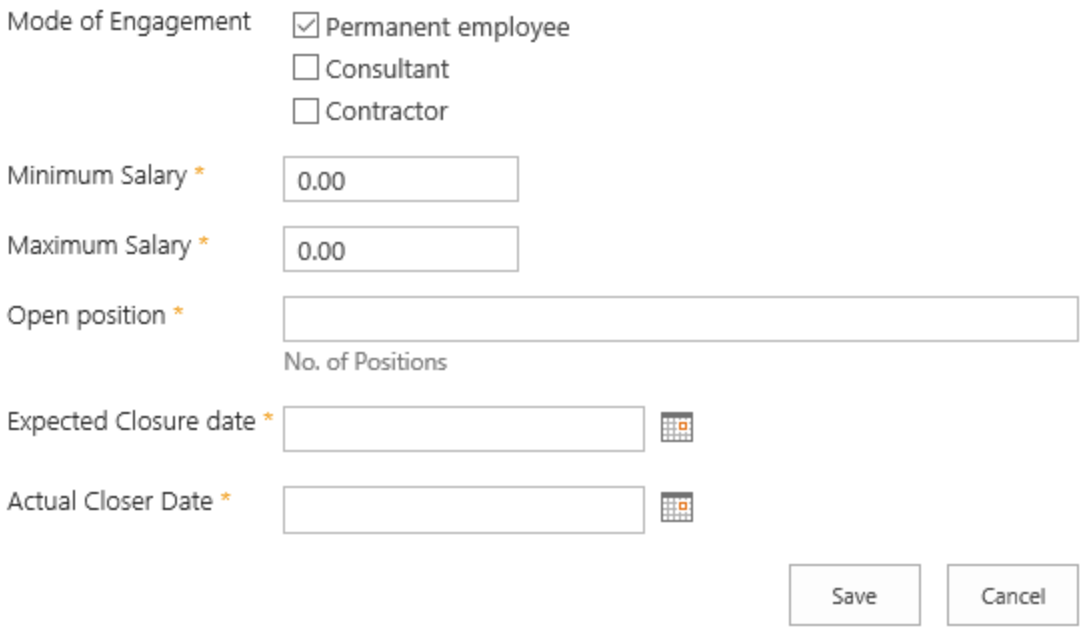


Display 5. Project Team Interface

RECRUITMENT

The Recruitment interface can capture the entire recruitment lifecycle – from raising an indent with information about open positions to recording interview outcomes followed by selection/rejection information. The project calendar interface will help schedule the interviews along with attaching the interview feedback.

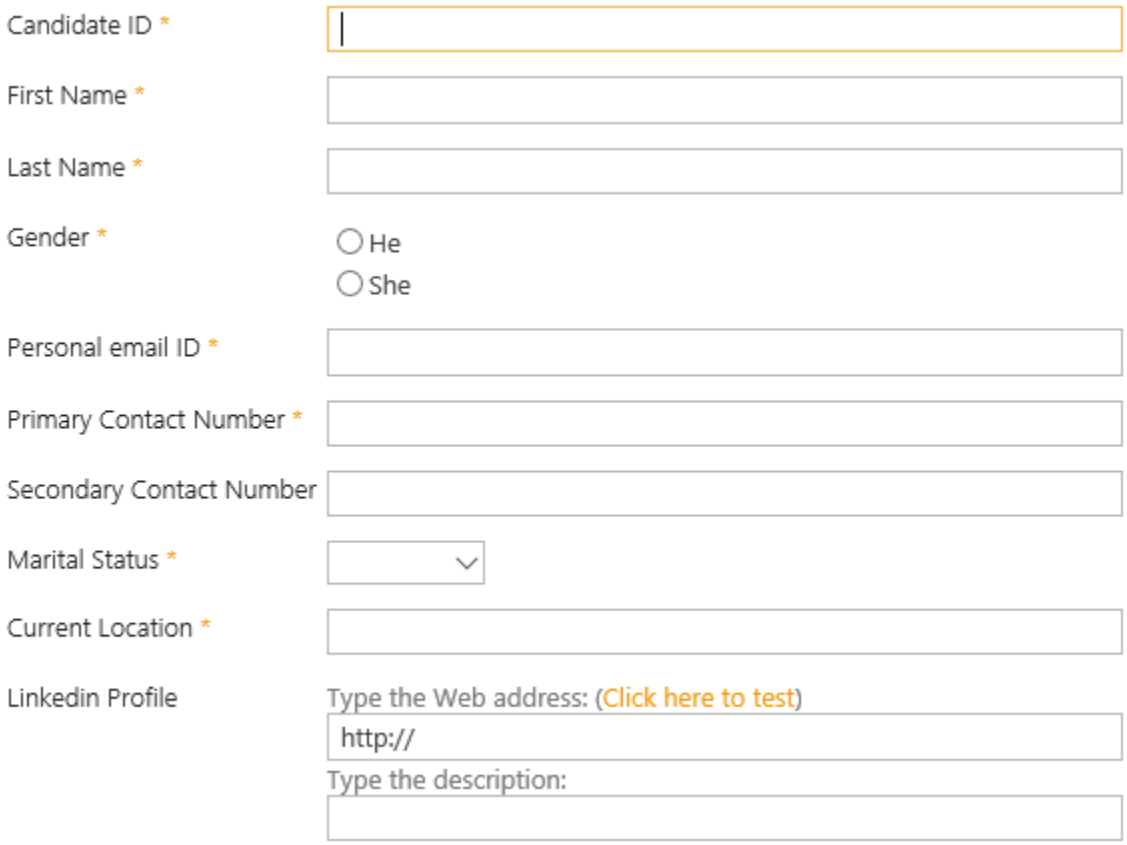


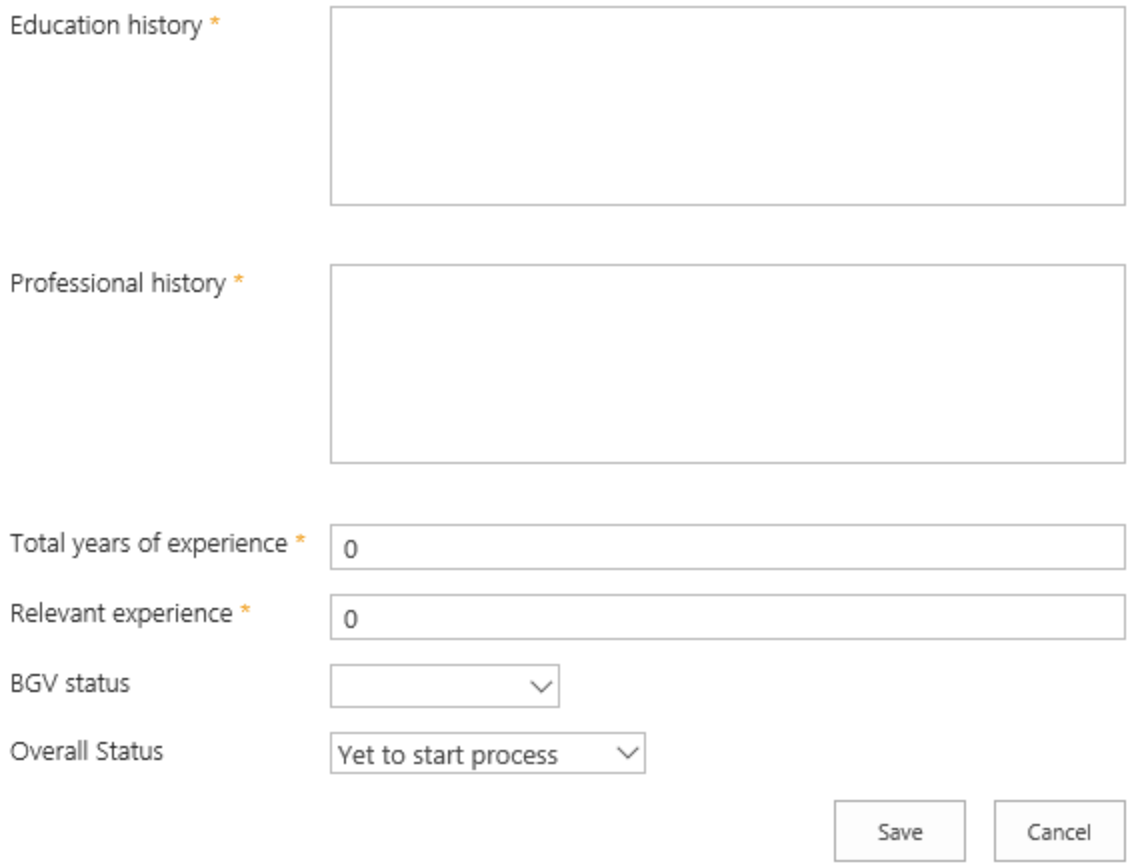


Display 6. Recruitment Interface

HR SCREENING

This window ensures screening information of the candidate is reviewed and recorded. The screening information could include the below shown fields (not limited to):

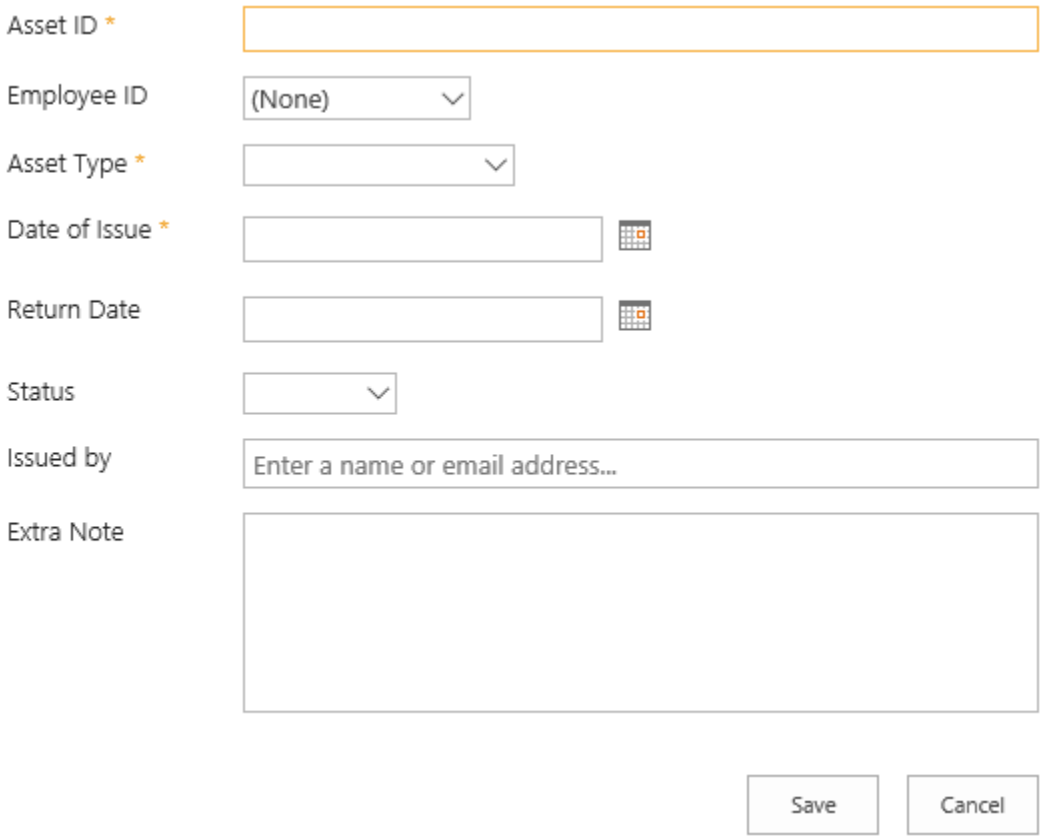




Display 7. HR Screening Interface

PROJECT ASSET TRACKER

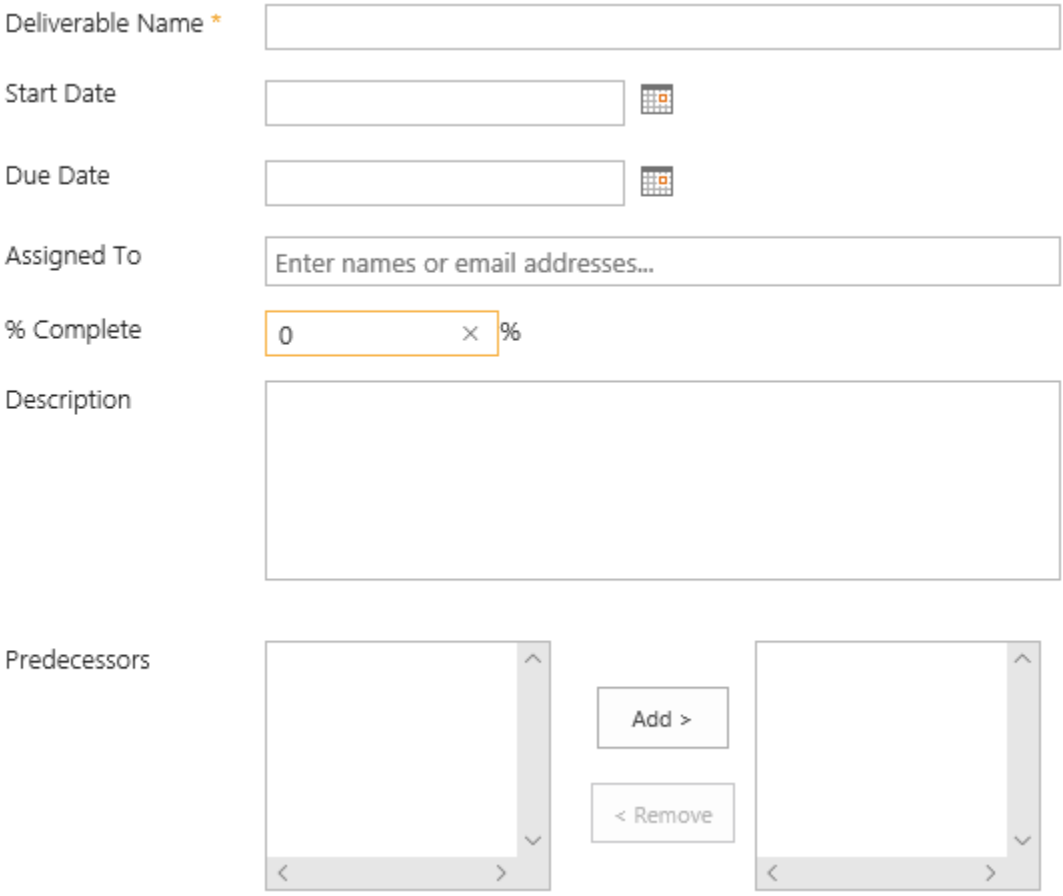
Assets including hardware/software assigned to project team members are tracked using this form which has details of the asset, date/return of the asset.

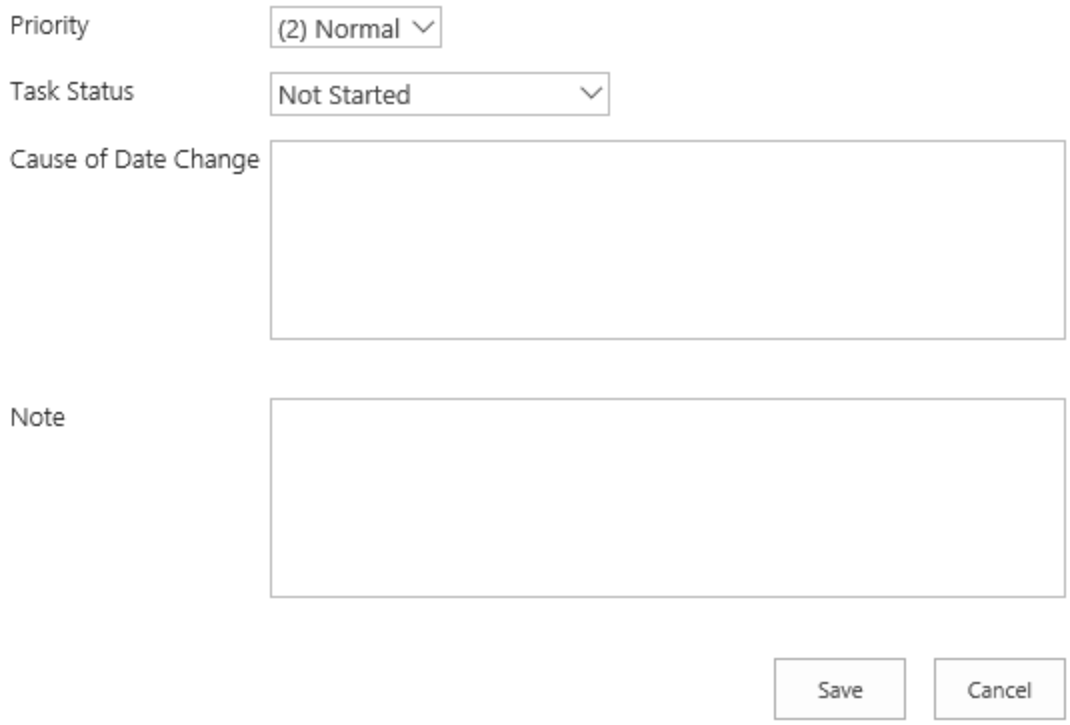


Display 8. Asset Tracking Interface

PROJECT DELIVERY TRACKER

Tracking project delivery is the key and it is important that the timelines are recorded and tracked on an ongoing basis to ensure customer satisfaction.

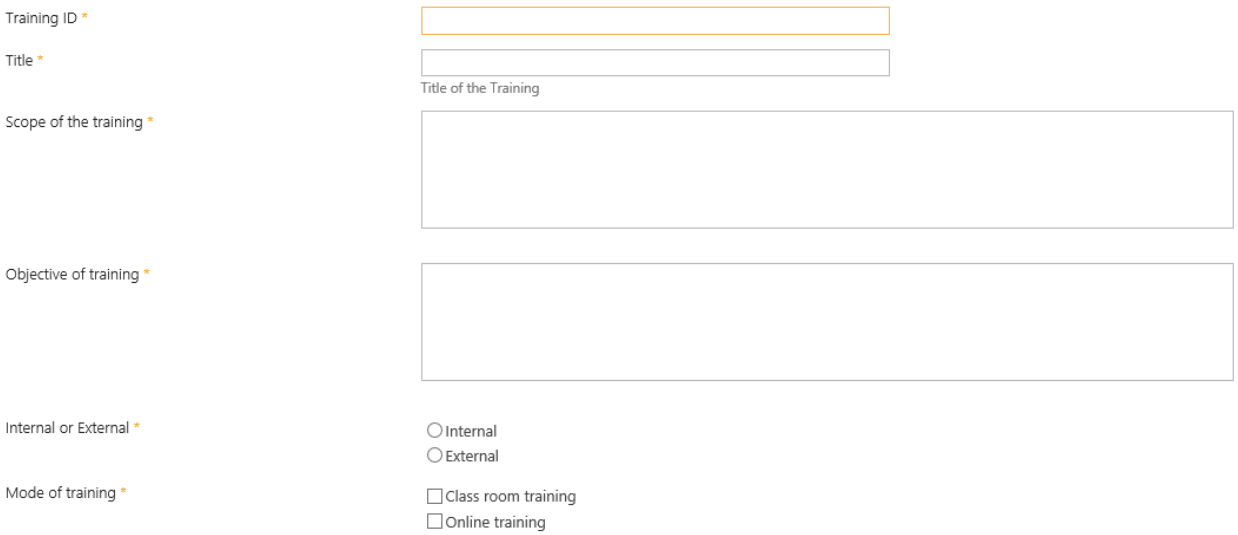


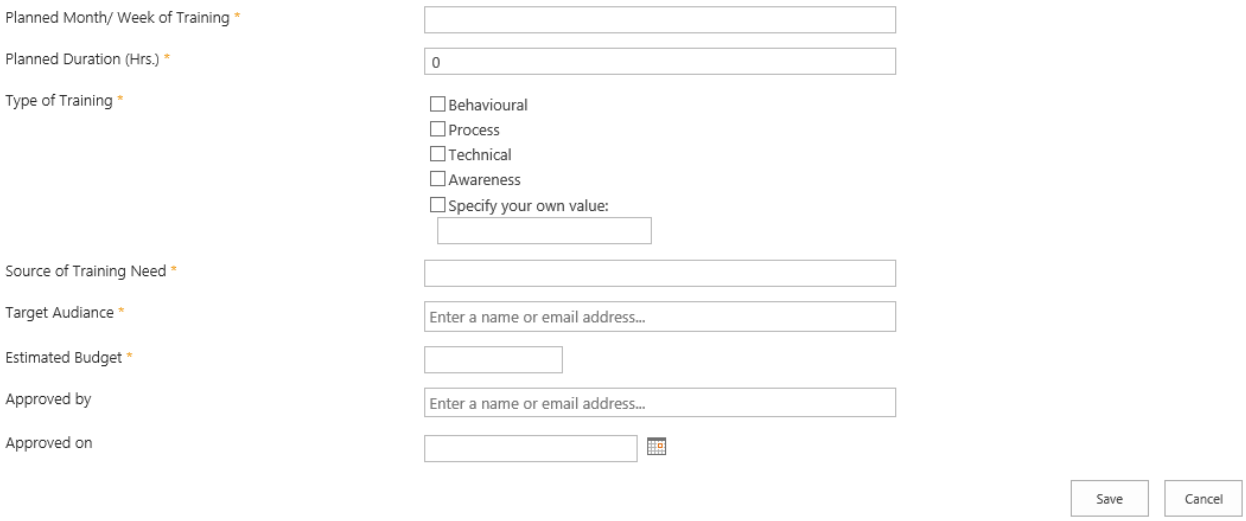


Display 9. Project Delivery tracking interface

PLAN THE TRAINING

Skilled resources are the key for any project. Hence it is important that necessary trainings related to the project/protocol is planned and necessary approval are obtained.

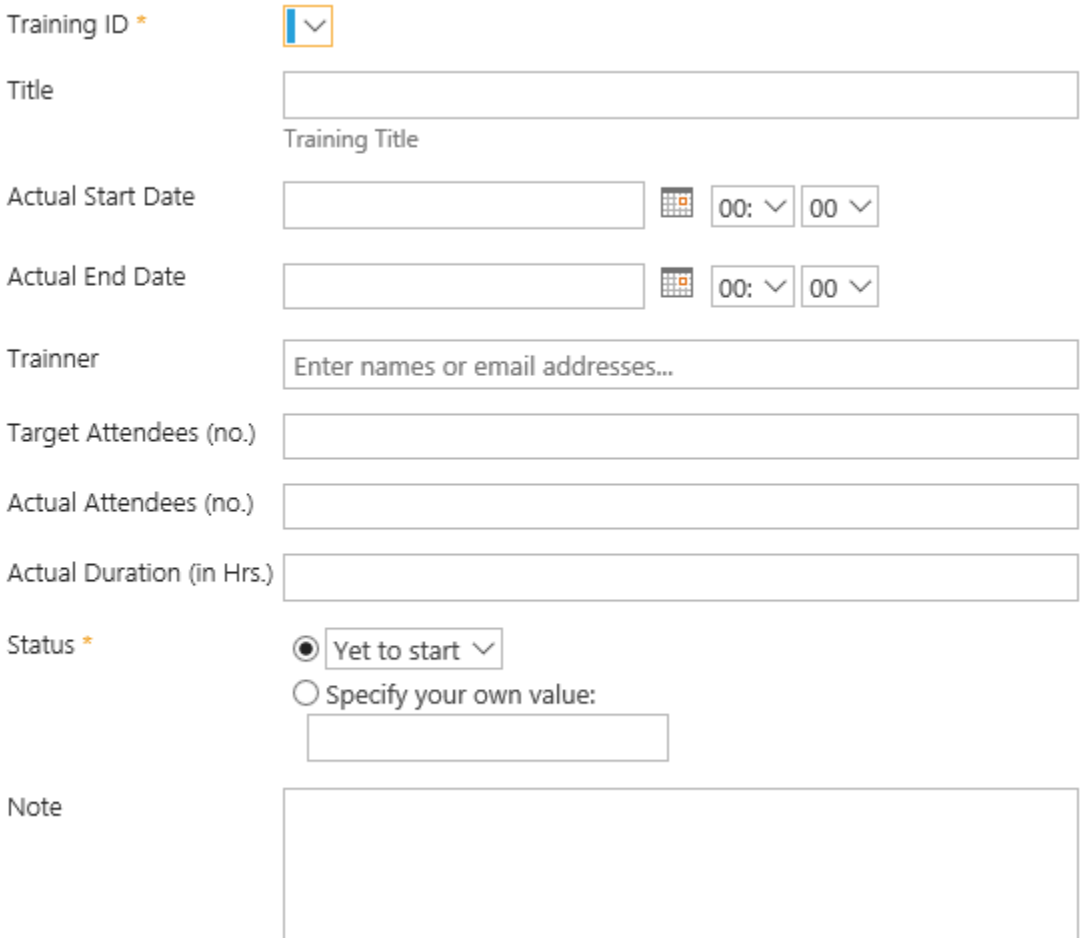




Display 10. Plan the Training interface

TRACK THE TRAINING

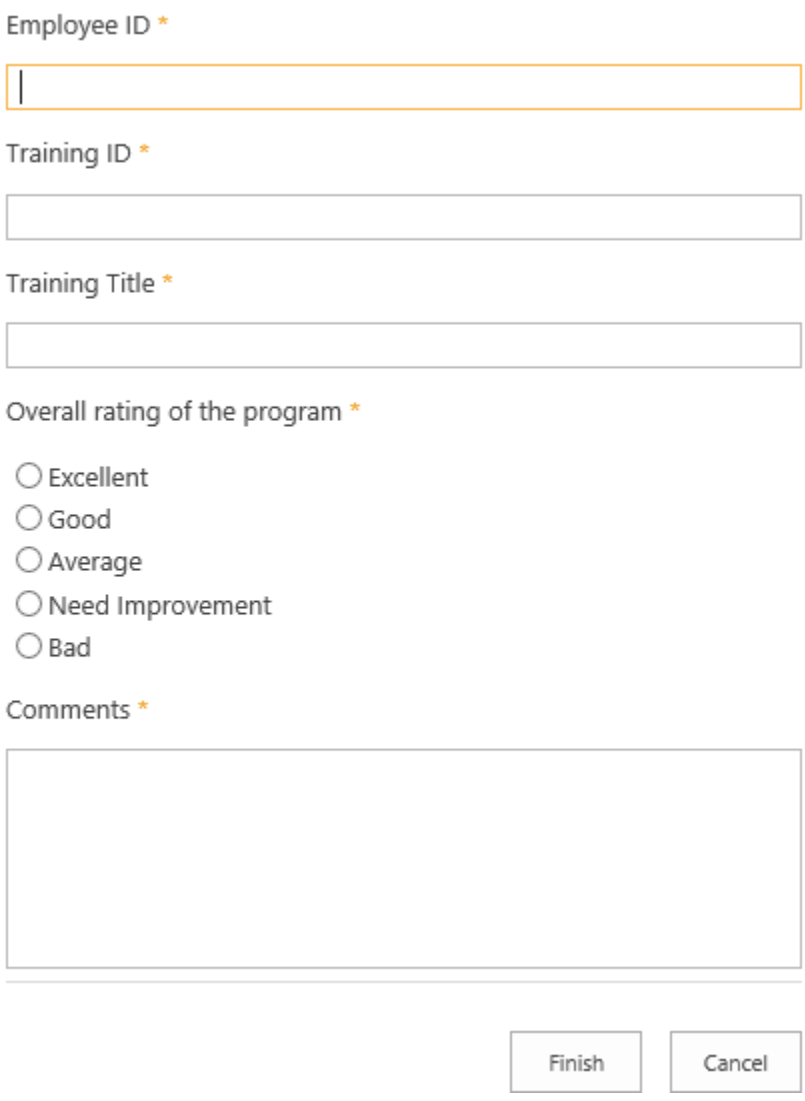
Based on the training plan, it is important that trainings need to be tracked to ensure completion and to analyze the data related to attendees and re-plan/re-schedule/re-train if necessary.



Display 11. Track the training interface

TRAINING FEEDBACK

Capturing training feedback is important in the learning and development cycle. This gives information regarding the quality of training imparted and helps the organization plan/organize in a much more acceptable way.



Display 12. Training feedback interface

ISSUE TRACKER

This is an important tracker in the project lifecycle. The project could have certain incidents; deviations; customer escalations; non-conformance reports from audits etc. Such information is captured in the tracker along with the risk associated and impact on subject safety/data integrity, if any. The issue can be linked to Corrective/Preventive action.

Issue ID *

Issue Title *

Category *

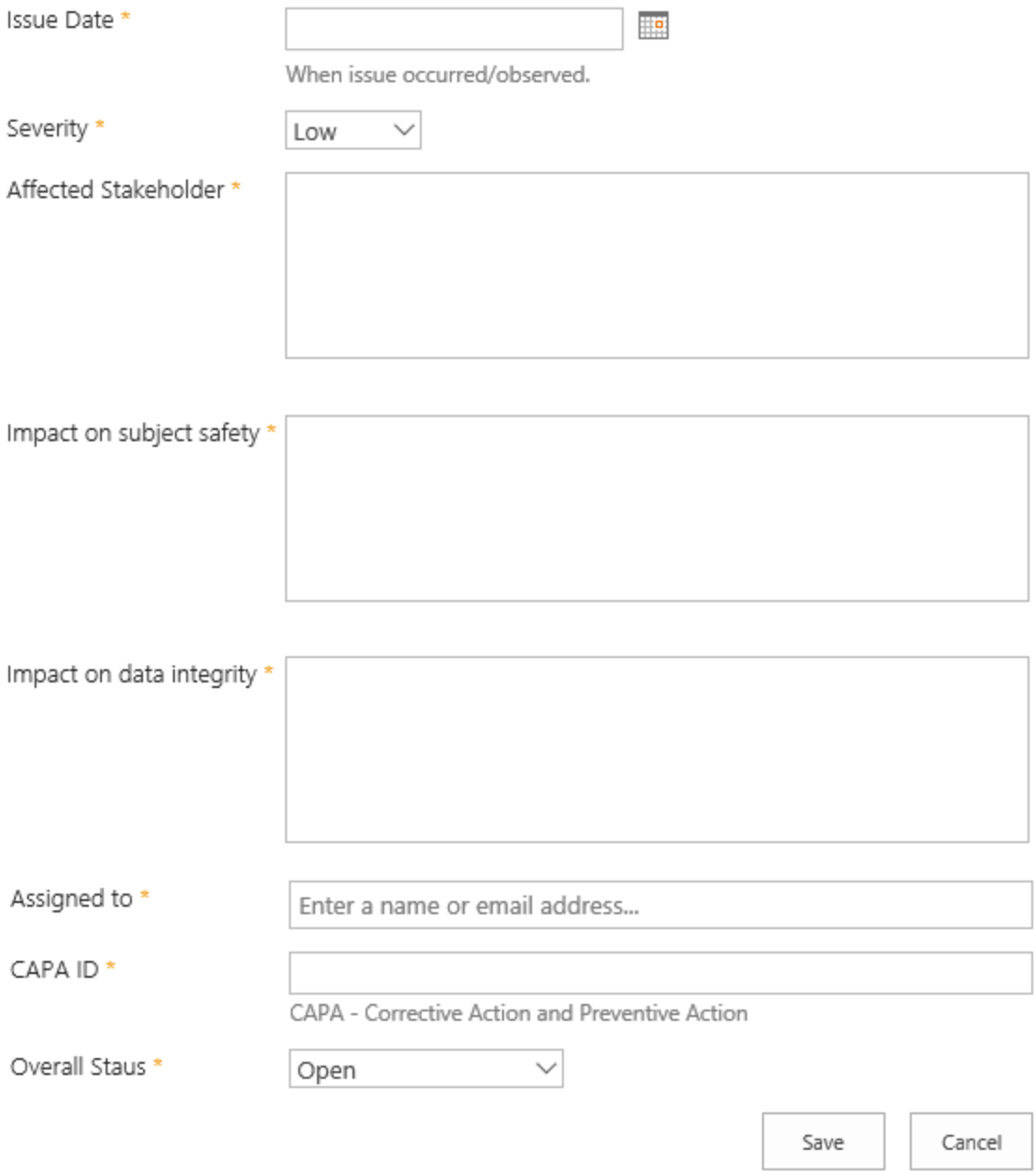
- ☐ Incident
- ☐ Deviation
- ☐ Customer Escalation
- ☐ Internal Audit NC
- ☐ External Audit NC

Description *

Please provide detailed description which covers:

1. What is the issue
2. When did this occur/happen
3. Where did this occur/happen

Associated Risk *

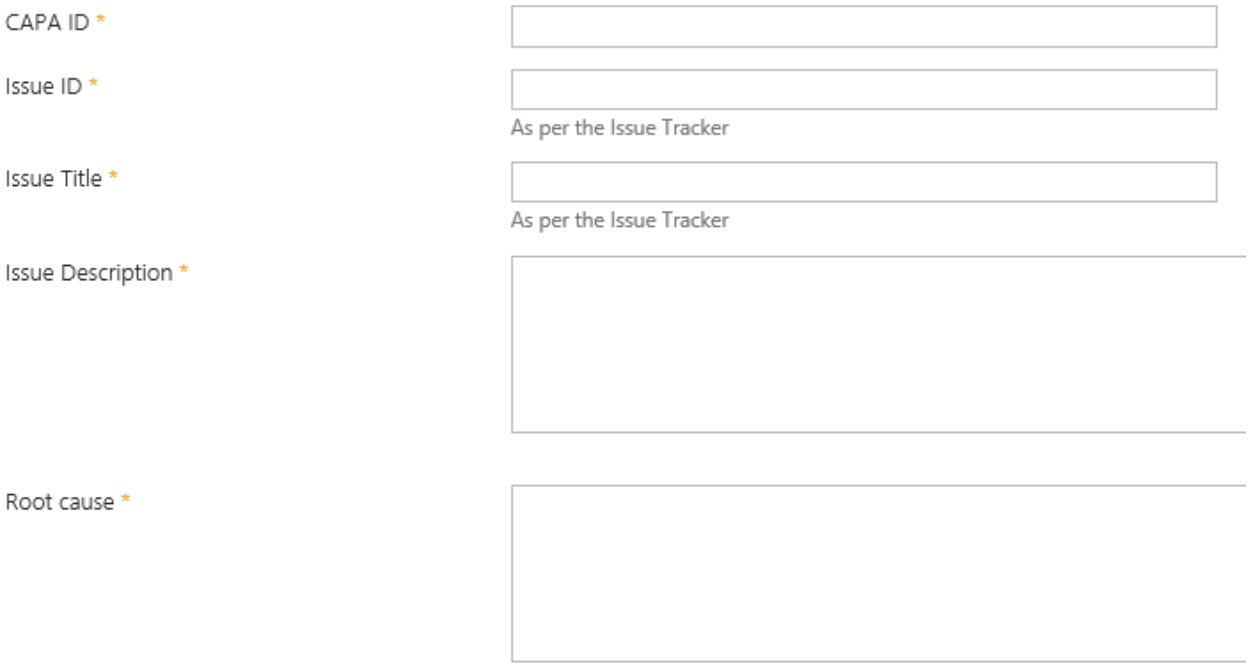


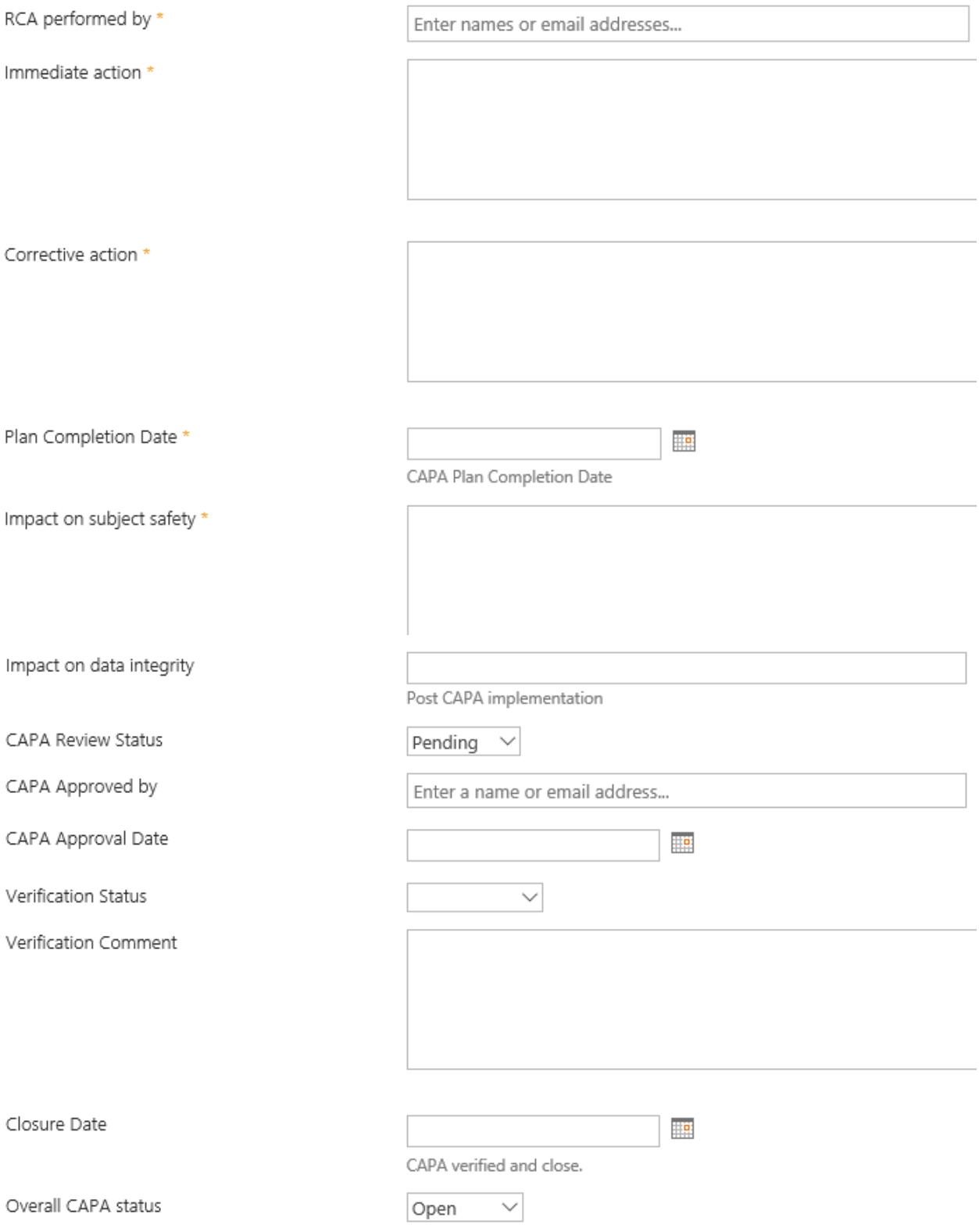
Display 13. Issue tracking interface

CAPA LOGS

Corrective and Preventive Action log view will include the following:

- Root cause
- Timeline to complete the CAPA
- Impact on subject safety/data integrity
- CAPA review and approvals
- CAPA implementation verification and closure information

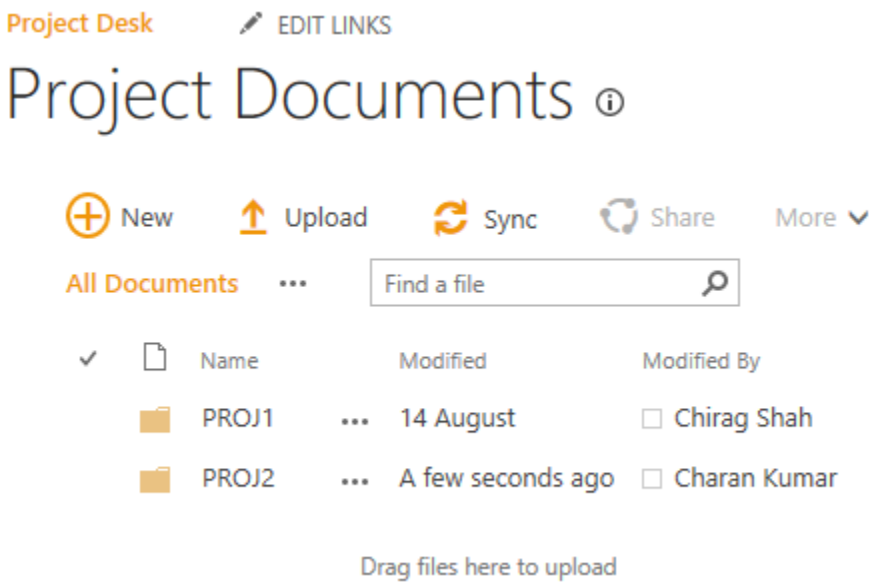




Display 14. CAPA Log interface

PROJECT DOCUMENTS

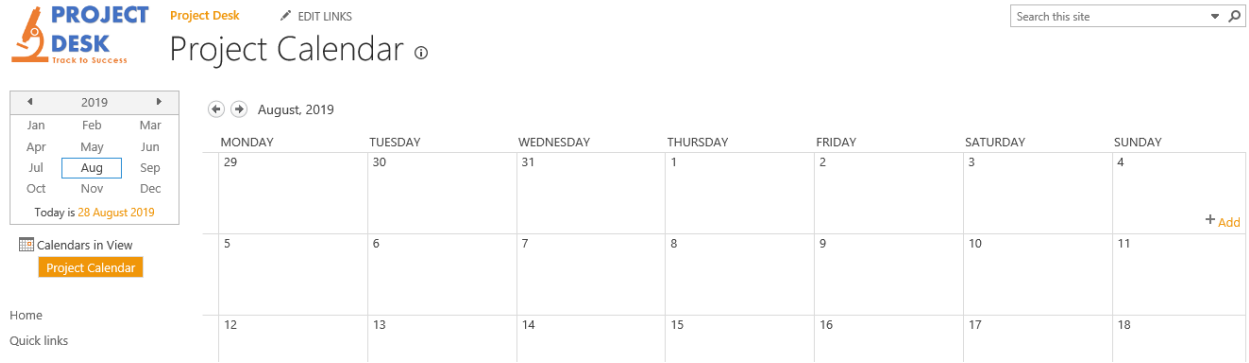
The project document repository can hold documents related to the project – protocol, specifications, data management plan, statistical analysis plan, SDTM/ADaM IGs, TLF files etc.



Display 15. Project document interface

PROJECT CALENDAR

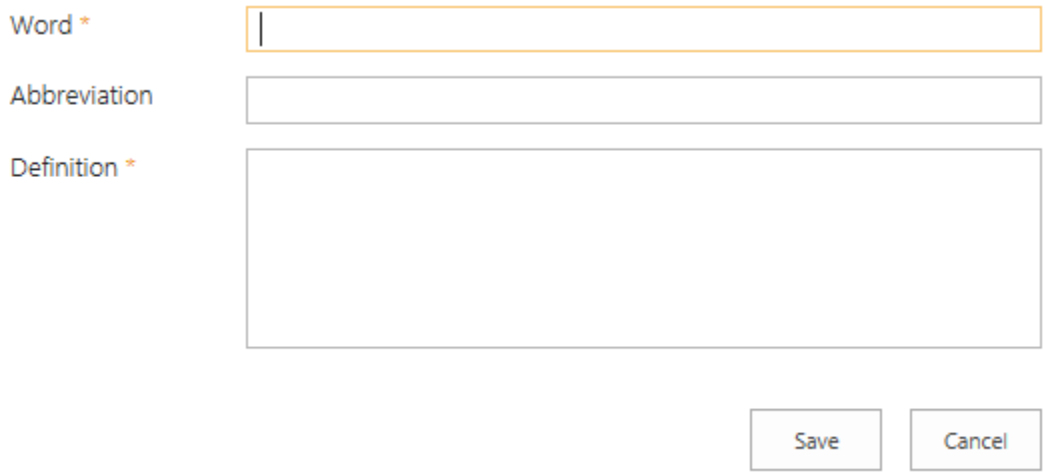
The tool also has an inbuilt feature to include a calendar which could be utilized to set meetings and track activities. This can be used to schedule interviews and also have interview feedback attached as a document.



Display 16. Project calendar interface

PROJECT ABBREVIATIONS & GLOSSARY

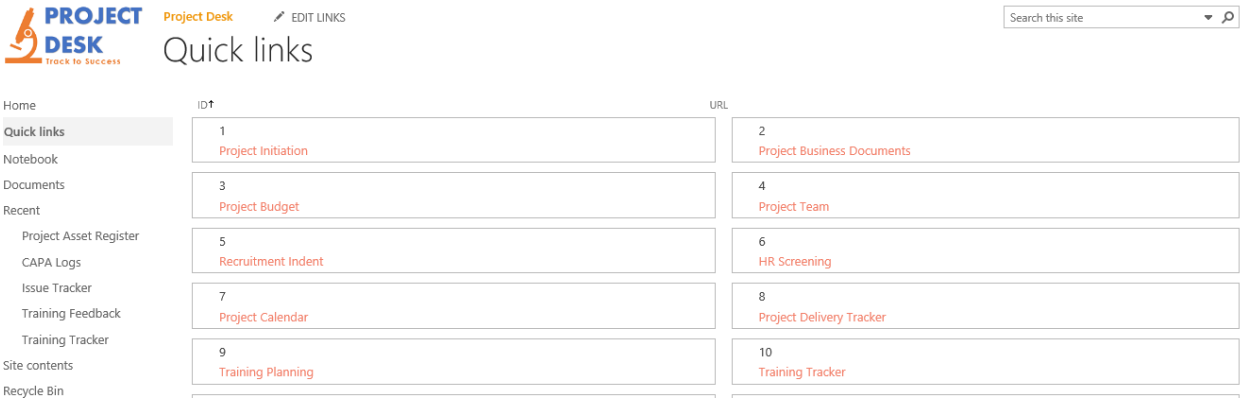
The project abbreviations and glossary could have certain information regarding the terminologies used in the project and its definition. The details could be recorded here.



Display 17. Project calendar interface

PROJECT DESK – SHAREPOINT BASED TOOL FOR PROJECT MANAGEMENT

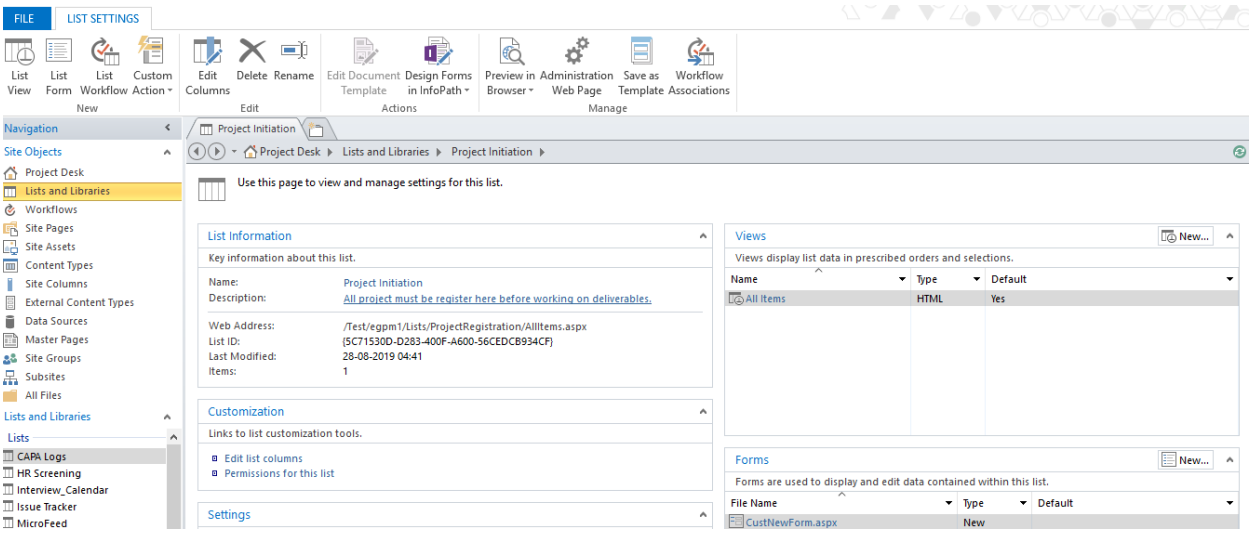
The final package will have a view as shown below with user-friendly easy-to-click form.



Display 18. Project Desk snapshot

The backend of the User Interface design would have objects, lists and libraries to be added/mapped.

For e.g.,



Display 19. Behind-the-scene interface

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CONCLUSION

Project management compliance to regulatory framework is of great importance. The tool only helps in fostering discipline with features such as audit trail, approvals before proceeding to next activities; data retrieval; having data summary available in presentable format – these are few features which would help us in ensuring compliance. Having hosted on a secure private cloud, the features related to information security too are adhered to. The importance of project management also lies with the ease of data analysis – which is easy in SharePoint modules – this feature helps in managing risk and increase the ability to take informed decisions. The tool is just one part of the project management activity; however the team is also important in bringing project management discipline – irrespective of the model followed – waterfall to agile etc.

It's important that the project manager and the team understand the objective of the project and roles involved, effective communication, effective usage of tools and techniques, culture to be held accountable and to be accountable and ensuring customer satisfaction at every levels form the basic essence of any project management process.

It is very important to utilize the existing resources and build a tool/framework for effective usage and Project Desk on SharePoint is an example of cost-effective project management design.

REFERENCES

PMBOK documentation

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