# Manage Your Clinical Studies Faster With ClinAction

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# 1. ABSTRACT

Last year, pharmaceuticals, medical device manufacturers and genetic research companies spent over 60 billion dollars developing new therapies. The Biotech industry conducts clinical trials requiring the collection and analysis of medical information for hundreds and thousands of subjects. Teams of SAS® programmers develop programs and reports to scrutinize and analyze clinical datasets to eliminate invalid data and avoid erroneous information to be submitted to the FDA. Errors can be costly, potentially costing millions in lost revenues each month the FDA delays approval for a new treatment.

ClinAction was specifically created to manage and collaborate on software development projects in the Biotech industry. Project managers achieve higher productivity by load balancing their resources, using an intuitive user interface. They can monitor resources allocation and expected end dates, and receive real time updates as tasks are completed. In addition, ClinAction facilitates collaboration with centralized project documents and a message board.

ClinAction demonstrates the flexibility and power of SAS/IntrNet. Our demo showcases the simplicity of ClinAction to create and manage study-related programming projects from the simplest SAS report, to the most complex EDC (electronic data capture) builds. We also demonstrate the system modularity, allowing project managers to customize and execute any type of reports they need to forecast, manage and allocate their project resources.

This paper will benefit clinical data managers and software project leaders interested in:

- Improving their team's productivity
- Tracking and forecasting their programming resource needs
- Generating project status and metrics reports.
- Learning about the power and features of SAS/Intrnet

# 2. INTRODUCTION

ClinAction is a SAS/IntrNet application designed to help managers organize projects and tasks. Designed for managing clinical studies, ClinAction is a web-based system to organize time and resource allocation and to ensure projects are delivered on time by tracking progress and project completion.

To host this dynamic web application, three main components should be configured: the web server, the application server and the database. Apache HTTP server 2.2 was chosen as our product web server, and SAS/IntrNet as the application server.

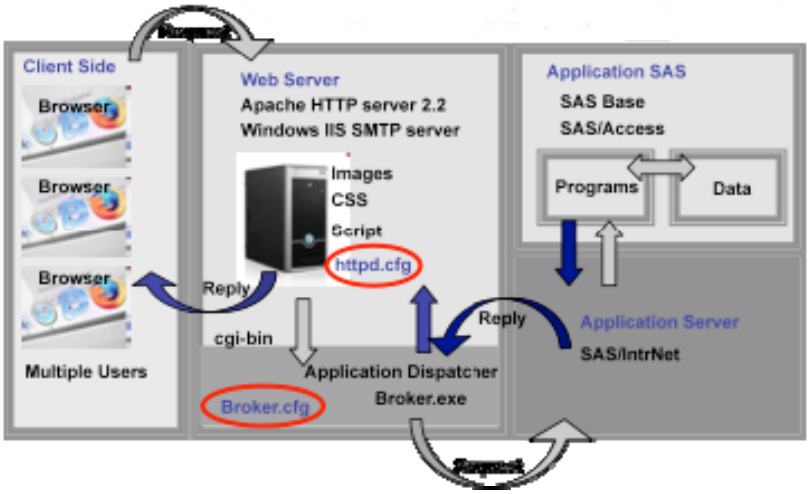


*Figure 1. Architecture of ClinAction*

# 3. A ROLE-BASED APPLICATION

ClinAction is designed as a role-based application; that is, features available to users vary according to their roles in a project. A single user can have different roles for different projects. Four types of users can interact with ClinAction: the administrator, the project lead, the resource lead and the resource.

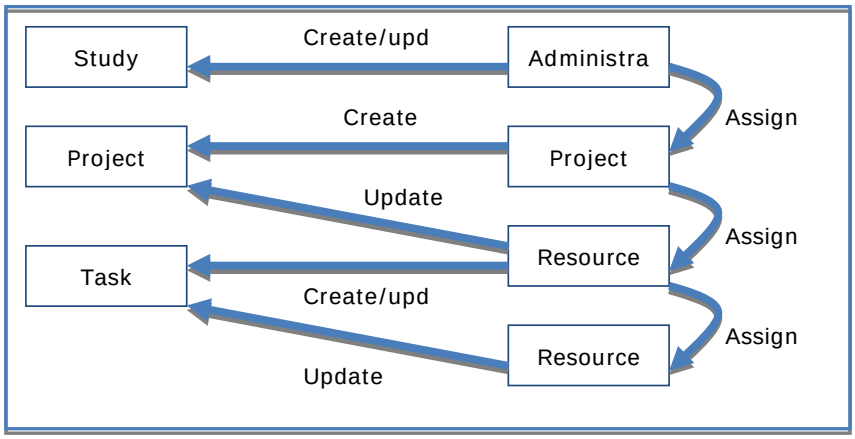


*Figure 2. User interaction with ClinAction*

# 4. AUTHENTICATION

The administrator is the only role allowed to create users.

The first time they log in, users have to reset their initial password and choose a recovery question in case they lose their password. The system will then recognize the different roles assigned to a user and it will enable or disable some of the features, depending on the user's role for a specific project.

## 4.1 ADMINISTRATOR ROLE

The administrator is the super-user of the application and has access to all functions. Multiple users can share the administrator role. Administrators create users, grant them access rights and can customize the application to fit the needs of the project or the organization. They can also create studies and assign project leads to them.

## 4.2 PROJECT LEAD ROLE

The project lead creates projects, specifying business due dates, priorities and other attributes. They also assign a resource lead to the project that will be responsible for executing the project.

## 4.3 RESOURCE LEAD ROLE

The resource lead creates project milestones and tasks, and assigns resources to execute the tasks. To help balance the workload, a resource workload dashboard shows how resources are allocated to current tasks.

## 4.4 RESOURCE ROLE

Resources are responsible for completing specific tasks and updating their completion status.

# 5. PROJECT MANAGEMENT

## 5.1 STUDY

ClinAction's primary goal is to enable pharmaceutical and biotechnology companies to manage projects for their studies.

## 5.2 PROJECT

A project is composed of milestones and tasks and is managed at three different levels:

Project details – These are attributes used to define a project, such as cost type, area (or department) name, resource lead, due date, status and so on. These attributes can be fully customized by an administrator to meet the organization needs; for example to define the specific cost types defined by the accounting department.

Project milestones – The resource lead defines the milestones for the project from a list of milestones previously defined by an administrator. By default, one milestone, Project end, is automatically created, using the project due date.

Tasks – The resource lead creates and assigns tasks to different resources.

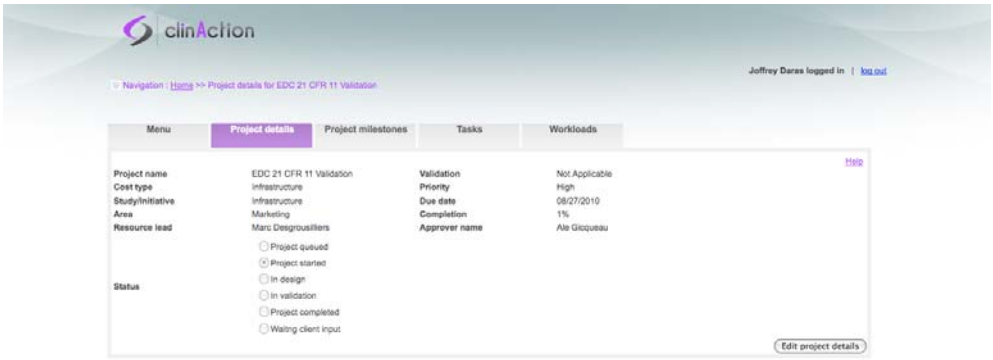


*Figure 3. Project detail view*

## 5.3 TASK

**Comment [MD1]:** Screen shot?

To execute a project, the resource lead creates and assigns tasks to be completed by the resources. A time estimate and a due date must be defined for each task. To ensure on-time project completion, resource leads

can optimally organize resource allocation and view task updates in real-time. They can also manage productivity by producing reports showing resources allocation and project metrics.

To minimize project management overhead, a resource simply checks the task completion status box when a task is done. This information is used to automatically update the project percent completion status.

## 5.4 DOCUMENTS SHARING

Comment [MD2]: Screen shot?

ClinAction allows users to share documents related to a project, providing the following benefits:

- Automatic document versioning if the same document is uploaded multiple times
- Automatic document naming based on: study name, project name, document name and version number
- Real-time access to the latest version without having to go through numerous emails and endless threads
- Organization of project documents by document type and author.

**SAS macro code for uploading a document:**

```
%macro processUpload;

          /*check the version of the document*/
          %let version=1;
          %let isFirstVersion=1;
          proc sort data=&theds; by projectid version name; run;
          data _null_;
                set &theds;
                retain isFirstVersion 1;
                where projectid=&projectid;
                if strip(name)= "&docname"  then do;
                      isFirstVersion=0;
                      call symput('version', strip(max(version,&version)));
                      call symput('isFirstVersion', strip(isFirstVersion));
                end;
          run;

   %let FILEEXT=%scan("&_WEBIN_FILENAME", -1, ".");
   %let A=%sysfunc(length("&FILEEXT"));
   %let B=%sysfunc(length("&_WEBIN_FILENAME"));
   %if &isFirstVersion eq 0 %then %do;
          %let version=%eval(&version+1);
```

```
    %end;

    %if &version ge 1 and &version <10 %then %do;
           data _null_;
               Filename =substr("&_WEBIN_FILENAME", 1, &B-&A-1);
                  out_Pathname =cats("&libPath","&studynm", "_", "&projectnm", "_",
"&docname", "_00","&version",".","&FILEEXT");
                  out_Filename =cats("&studynm", "_", "&projectnm", "_", "&docname",
"_00","&version",".","&FILEEXT");
                  out_Docname =cats("&studynm", "_", "&projectnm", "_", "&docname",
"_00","&version");
                  call symput('in_Filename', strip(Filename));
                  call symput('out_Pathname', strip(out_Pathname));
                  call symput('out_Filename', strip(out_Filename));
                  call symput('out_Docname', strip(out_Docname));
           run;
    %end;
    %else %if &version ge 10 and &version <100 %then %do;
           data _null_;
               Filename =substr("&_WEBIN_FILENAME", 1, &B-&A-1);
                  out_Pathname =cats("&libPath","&studynm", "_", "&projectnm", "_",
"&docname", "_0","&version",".","&FILEEXT");
                  out_Filename =cats("&studynm", "_", "&projectnm", "_", "&docname",
"_0","&version",".","&FILEEXT");
                  out_Docname ==cats("&studynm", "_", "&projectnm", "_", "&docname",
"_0","&version");
                  call symput('in_Filename', strip(Filename));
                  call symput('out_Pathname', strip(out_Pathname));
                  call symput('out_Filename', strip(out_Filename));
                  call symput('out_Docname', strip(out_Docname));
           run;
    %end;



    /*Save the uploaded file into the library*/
    data _null_;
           infile  "&_WEBIN_FILEREF" recfm=n;
           file "&out_Pathname" recfm=n;
           input byte $char1.@;
           put byte $char1.@;
    run;
```

```
    /*Update dataset Document*/
    proc sql noprint;
       select max(id)+1 into :ID from &theds;
    quit;
    proc sql noprint;
       insert into &theds
             set name="&docname",
                      id = &ID,
                         description="&docdescp",
                         typeid=&typeid,
                         projectid=&projectid,
                         date=input("&crtdt", mmddyy10.),
                         filename="&out_Filename",
                         isArchived="0",
                         version=&version,
                         authoruid="&authoruid";
    quit;

    /*GUI output*/
/*  data _null_;
          file _webout;
                 put"<Script language = JavaScript>";
                put" window.top.window.stopUpload();";
               put"</Script>";
    run;
*/
%mend processUpload;
```

## 5.5 MESSAGES

Comment [MD3]: Screen shot?

People involved in a project can collaborate by sending messages. ClinAction acts as the central repository for all project communication. Optionally, a message copy can be sent through email.

## 5.6 REPORTS

Comment [MD4]: Screen shot?

ClinAction data is stored in SAS datasets. The report feature extracts data from the SAS datasets and generates reports in Excel or PDF formats.

Excel reports are generated using Dynamic Data Exchange (DDE), which requires SAS/ACCESS.

The power of SAS report distribution helps create reports that match users' needs. Simple queries constructed on the client side are passed through a web server to the data repository. It is then formatted as a report to be

viewed on the client side. The report can be output in different formats. We chose Excel, PDF and graphic charts for our reports.

Using Excel, reports can be further customized or enhanced. Reports in PDF format can be readily used in project status meetings or data support.

ClinAction also provides charts and graphics reports; for example, pie charts show at a glance how resources are allocated over different projects.

**SAS code for generating excel reports:**

```
%let rc=%sysfunc(appsrv_header(Content_type, application/vnd.ms-excel));
             %let    rc=%sysfunc(appsrv_header(content-disposition,    %str(attachment;
filename=&filenm..xls)));
             /*ods path temp.tmplmst(read) sashelp.tmplmst(read);*/
             ods listing close;
             OPTION LeftMargin = .5in
                    RightMargin = .5in
                       TopMargin = .5in
                       BottomMargin = .5in;
             ODS TAGSETS.EXCELXP
                    FILE=_webout
                    style=statdoc
                    OPTIONS(sheet_Name = 'Area Summary'
                           sheet_interval='None'
                              Orientation= 'LANDSCAPE'
                              Embedded_Titles = 'yes'
                              Autofilter = 'All'
                              default_column_width="10, 10, 15, 10, 12, 7, 7, 10, 10,
10, 10, 10"
                   width_fudge='0.75');


             Proc report data=tasks  nowd split="|" spacing=3 missing headline;
                    column studynm projectnm name plfullname rlfullname    pjstatus
esthours acthours startdt enddate cmplflag prioritynm;
                    define studynm /display center  "Study name";
                    define projectnm /display center  "Project name";
                    define name /display center  "Task name";
                    define plfullname /display  center   "Project lead";
                    define rlfullname /display  center   "Resource lead";
                    define pjstatus /display center  "Project status";
                    define esthours /display center   "Estimated hours";
                    define acthours /display center  "Actual hours";
```

```
        define startdt /display  center  "Start date";
        define enddate /display center   "Due date";
        define cmplflag /display center  "Task status" f=cmplflag.;
        define prioritynm /display center  "Task priority";
        title "Summary for user : &rfullname ";
run;

ODS TAGSETS.EXCELXP CLOSE;
ODS listing;
```

# 6. ADMINISTRATION

## 6.1 CUSTOMIZABLE APPLICATION

ClinAction is fully customizable to meet the needs of a research organization. All dropdown lists correspond to values saved in a SAS dataset. Each keyword related to a value is changeable by an administrator in the GUI. For example, administrators can define their own cost types, project milestone types, project status types, document types, etc. The selected keywords will be displayed in dropdown lists to the users.

ClinAction is very flexible and adaptable to meet any departmental needs.

## 6.2 AUDIT TRAIL

ClinAction has a powerful audit trail capability to record all the user's changes. This is an important feature for the pharmaceutical and biotechnology industry as it is required for 21 CFR Part 11 compliance.

A powerful macro, shown below, has been developed and is triggered each time a user updates sensitive information in ClinAction.

The macro is saved into the file "w_savefield.sas". It detects the parameter, which is the value that has been changed and that needs to be audited. It then saves several variables such as the date, the description, the reason and the action (create, edit, delete) into the audit dataset.

**SAS macro code for audit trail :**

```
/*------------------------------ Milestone begin ---------------------------*/
      %if "&param" eq "mlstnLst" %then %do;
            %LET auditds = audit.amilestone;
            %IF %SYSFUNC(EXIST(&auditds)) eq 0 %THEN %DO;
                  data &auditds;
                        attrib timestamp label='Date/Time' format=datetime20.
                                 name length=$40 label='Name'
                                 reasons length=$400 label='Reasons'
                                 action length=$8 label='Action'
                                 userid length=$40 label='User ID'
                                 ID label='ID';
                        set &theds (keep= id name);
                        timestamp = datetime();
                        action = 'create';
                        userid = 'system';
                  run;
            %END;
            proc sql noprint;
```

```
                insert into &auditds
                        set id = &milestonelstid,
                               name = "&milestonelstnm",
                               reasons = "&reasons",
                               timestamp = datetime(),
                               action = "&mode",
                               userid = "&save_uid";
        quit;
    %end;
```

clinAction

History of task-ID '60'

| Date/Time | Name | Project ID | Task Type | Area | Priority | Resource | Start Date | End Date | Est Hours | Actual Hours | Completed | Reasons | Action | Performed By | ID |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 27JUL2010:11:59:19 | Google earth | 23 | 1 | 8 | 2 | olga | 09AUG2010 | 20AUG2010 | 10.0 | . | 0 | | create | sophie | 60 |
| 10AUG2010:17:49:34 | Google earth | 23 | 1 | 8 | 2 | olga | 09AUG2010 | 20AUG2010 | 6.0 | . | 0 | estimated hours | edit | sophie | 60 |
| 10AUG2010:17:53:01 | Google earth | 23 | 1 | 8 | 2 | olga | 09AUG2010 | 20AUG2010 | 4.0 | . | 0 | wrong hours | edit | sophie | 60 |
| 11AUG2010:00:30:22 | Google earth | 23 | 1 | 8 | 2 | olga | 16AUG2010 | 20AUG2010 | 4.5 | . | 0 | change time | edit | sophie | 60 |
| 13AUG2010:12:00:30 | Google earth | 23 | 1 | 8 | 2 | olga | 23AUG2010 | 25AUG2010 | 4.5 | . | 0 | change due date | edit | sophie | 60 |
| 17AUG2010:15:30:15 | Google earth | 23 | 1 | 8 | 2 | olga | 13SEP2010 | 16SEP2010 | 6.0 | . | 0 | changed due date | edit | sophie | 60 |

Close [x]

*Figure 4. Project history (audit trail) view*

### 6.3 EMAIL FEATURE

ClinAction notifies users about project and task changes by sending email using the SMTP protocol. SMTP is a service provided by IIS. Delivery of message is initiated by transferring the message to a designated SMTP server. Users can enable or disable this function in their profile.

**SAS macro code for sending email:**

```
%Macro sendmail(To=, From=, CC=);

    %LET _PGM = w_adm_setupURL;
    %LET setupds = sdata.setup;
        %IF %SYSFUNC(EXIST(&setupds)) eq 0 %THEN %DO;
            %let URLvalue=http://clinAction.clinovo.com;
        %END;
```

```
            %ELSE %DO;
                  data _null_;
                        set &setupds;
                        where strip(itemname)= "URL";
                        call symput('URLvalue', strip(itemvalue));
                  run;
            %END;


      %if "&mode" = "create" %then %do;
            filename emailout email "NULL";
            %let rleadname=%sysfunc(propcase(&resourceuid));
            data _null_;

                  file emailout to="&remail_addr"
                                    from="&From"
                                 cc="&CC"
                                subject="Task ID &id : Automated new task
notification"
                                type="text/html";;
                  put "Dear &rleadname, <br>";
                  put "ClinAction has created a new task. <br>Task
ID:<b>&id</b><br>Task name: <b>&tsknm</b>.<br><br>"/
                        "You are assigned to be the resource. Please login to "/
                        "ClinAction (&URLvalue) to see the task detail.<br> If any
problem, please "/
                        "notify clinactionAdmin@clinovo.com immediately.";
            run;
      %end;
%Mend sendmail;
```

# 7. BENEFITS OF CLINACTION

ClinAction is a cutting-edge SAS-based solution developed to manage projects and tasks related to clinical studies. It provides managers and resources faster, accurate and up-to-date projects information.

ClinAction leverages the powerful capabilities of SAS, the indisputable leader in business intelligence. It implements a web-based application accessible from any internet browsers, anywhere in the world.

Using the SAS IntrNet application platform, ClinAction is a superior solution than the traditional approach based on Excel spreadsheets and email communication.

ClinAction benefits include:

- Enhanced productivity – Organizes a team's deliverables and activities for on-time project completion.
- Reporting – Allows managers to track resource allocation and project status efficiently.
- Project planning and tracking – Task time estimates versus actual can be monitored. Provides real-time updates on projects and tasks status to ensure projects are completed on schedule.
- Improved project collaboration – Enables project communication within the project team, thus keeping everyone informed and organized.

# 8. CONCLUSION

ClinAction is a fully customizable project management tool that can easily meet the needs of any biotech company. In this role-based application, users have a clear understanding of their tasks and role within a project. Managers are kept informed in real time about project and task statuses.

Because it is web-based, ClinAction can be accessible from anywhere. Its powerful SAS data extraction technology provides meaningful and fully customized project management reports.


## ACKNOWLEDGMENTS

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## CONTACT INFORMATION

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