

## Clinical MART script

The clinical Modeling and Resource Tracking blueprint is a web-based planning and analytical tool that helps clinical researchers better plan, forecast and optimize their clinical trials.

This demonstration is from the perspective of a contract research organization, or CRO, but the driver based methods and analyses that the blueprint employs are equally suited to sponsor organizations. Indeed this blueprint builds on and extends some of the capabilities first introduced in IBM Cognos' other clinical blueprints, especially the clinical enrollment and clinical forecasting blueprints that are also available to IBM Cognos customers.

Clinical trial organizations face increasing pressures on a variety of fronts, in addition to regulatory pressures, clinical studies are becoming more complex with increased numbers of large global studies and smaller but more unpredictable adaptive studies.

Managers attempting to cost and track studies face real problems coordinating the many moving parts, compounded by delays and inaccuracies introduced by email, paper and manual spreadsheets. To further complicate matters, each part of the organization often appears to have their own set of number and their own version of the truth. It's a recipe for - if not disaster - then certainly high levels of stress inducement!

In addition to the cost and resource pressures faced by the study sponsors, contract researchers are also required to show a profit from running the studies. Without a firm grasp of the moving parts and application of standardized driver based approaches many hours are wasted assembling data and debating the numbers, rather than on higher value activities such as discussing progress and issues with the study teams and support staff.

The IBM Cognos Clinical Modeling and Resource Tracking - or MART - blueprint represents a way to remove many of the barriers to accurate and efficient forecasting and tracking - and to ultimately drive success - whether that means reducing costs, optimizing resources or managing cash and profitability.

IBM Cognos MART blueprint is a driver based model of an entire study and a collection of dashboards and analytical reports integrated on the IBM Cognos 8 Performance management platform. The model collects all the drivers or inputs that are essential to build the study model: recruitment funnel, contracts, patients, meetings and support resources. Multiple versions enable tracking of actuals and forecast versions against the original budget and contract scenarios. What if capabilities are fully supported. The ability to change data and see immediately the impact on costs, revenues and staffing requirements is an especially powerful feature

Ultimately the blueprint can remove many of the manual process steps and spreadsheets from the equation, providing increased control, audit trails, process

tracking and the ability to share information seamlessly with decision makers in an on-demand web-based environment

The blueprint contains an incredible amount of sophisticated capabilities in a pre designed template that takes much of the guess work out of implementing this type of tool. Our experts at the IBM Cognos Innovation Center - in collaboration with customers - have designed a best practice template that your organization can use as an accelerator to speed deployment.

The MART blueprint breaks down the process into 32 separate stages or cubes, to mirror the logical approach to setting up a study budget, and then tracking it through it's stages. The IBM Cognos model then crunches the numbers in real time, performing many millions of sophisticated calculations and presenting the results in reporting and analytical cube views so that managers can see the impact of changing drivers instantly.

When I access the IBM Cognos portal, I am presented with a display of key indicators and analytical charts tailored to my role in the organization. I have different tabs with different dashboards, such as profitability or recruitment. If I take a look at the recruitment dashboard I can see a summary of recruitment performance. This lets me see at a glance how I am doing and provides the capabilities to conduct deeper analysis on demand. Here I am looking at the recruitment for the UK. They appear to be forecasting significantly above budget. I'll need to take a closer look since this could be good news or bad news.

The next dashboard presents a cumulative enrollment chart that lets me understand visually the "patient funnel" that is a key performance measure.

I also have access to resource capacity information. This chart lets me compare the available hours with the demand, helping me identify resource bottlenecks or - as is the case here - surplus capacity that I may choose to allocate to other studies.

Let's look in more detail at some of the modeling and forecasting capabilities offered by the blueprint. When I access the plan, I see workflow data related to the studies in my area of responsibility and get an immediate feel for the status of our planning process. The different colors represent different statuses and I can email my team directly from this screen or look at audit data to see the last changes that were made to the plans.

I'll drill down into the plan for this study - number 114 - to update some of the assumptions or drivers as I suspect there are issues with the forecast.

When I access the model I am presented with a complete financial picture of the study, including contract, budget forecast and other sandbox plan versions. The blueprint calculates forecast data down to a low level of detail if I choose and is designed to accommodate the most complex forecast scenarios. Normally this type of sophisticated

and rule-driven forecast is only available in a spreadsheet but here I am working in an enterprise tool with all the control and scalability that entails.

Starting with summary data, the studies are typically planned with dates. The STUDY SUMMARY screen lets us input the key dates that will drive calculations in the model and will determine automatically when the costs that relate to those dates will occur

### RECRUITMENT FUNNEL

The most important cost driver and the most critical aspect of clinical planning is to get the recruitment and enrolment forecast right, since that drives much of the cost. In this scenario I increase the number of patients at the UK sites by 100. Notice how some of the data turns blue, representing changes in the data. These inputs are impacting downstream costs, such as investigator payments and other costs that change with recruitment. I can also adjust the percentage success rates at each stage of the funnel to give a more accurate forecast and to better reflect reality.

PATIENT COUNTS gives us a summary report of the recruitment funnel for each country by version. Note again the changed forecast data in blue.

The VISIT STAFF REQUIREMENTS tab gives an idea of the level of detail we can forecast at. Here I am forecasting in minutes per task how long my resources will spend at each visit. I could enter the data by hours or even days instead. The blueprint covers all configurations without any time consuming customization.

Notice how easy it is to change the values. To increase by a percentage I simply type I.N.C. 30 in the cell.

Another example is the meeting item, where I can specify additional staff required at the investigator meeting. In the background the blueprint calculates the impact on costs, revenue, cashflow and even the requirement for “research nurses” at the time specified for the visit.

RECRUITMENT ALLOCATION is where I can adjust the calculated values for the recruitment curves. By simply typing over the totals the tool will back calculate the weekly values in proportion, or I can delay the timing and update the enrolment curve, in this case delaying the enrolment for USA sites until September 1.

WEEKLY ENROLLMENT gives me the cumulative position and, again, I can choose to override the calculated forecast values.

Paging back to the SUMMARY tab, I can see the impact of these changes on my forecast, displayed in blue.

I have a lot of analytical capability in the plan and can easily drill down to the country or site level to see the impact of the changes in more detail. I can also drag and drop rows and columns to “slice and dice” the data. And with the IBM Cognos performance

management system I have automatic access to a range of more in depth analytical tools and reports.

When I open the patient counts tab in QUERY STUDIO I have access to all the other data in the planning model and can quickly create my own reports and charts to share with decision makers. I can save the report, or send it out in .pdf or excel format. I have full drill down capabilities here as well and can format the data as a chart with one click of the mouse.

So in summary, I have taken the incredibly complex process of budgeting and planning a clinical trial and built a model in an enterprise tool, totally removing manual spreadsheets from the equation.

All aspects of my resource plan including:

- Patient enrolment funnel
- contracts and milestones
- payments, costs and revenues
- and staff resources, both demand and supply

have been modeled in a flexible driver based environment that does not involve complex coding or customization

The MART blueprint is an accelerator that is designed help you quickly and effectively deploy IBM Cognos technology to rapidly realize return on investment and get a real grip on managing your clinical trial resources.

For a full list of IBM Cognos Performance Blueprints available for other functional areas in your organization please visit the IBM Cognos Innovation Center at [www.ibm.com/cognos/innovation-center](http://www.ibm.com/cognos/innovation-center).

Thank you for your interest in this *Blueprint*.