



Balancing the Books: Clinical Project Management on a Budget

Delivering projects on budget has become a predominate performance metric in clinical trials. CROS NT Project Manager, Mark Campbell, explains how to effectively complete projects on time and on budget without sacrificing quality.

Delivering projects on budget and sacrificing time, quality or employee satisfaction, is a paradox afflicting organisations, which can be avoided. Effective project management can be the answer to this problem.

The nature of projects and outsourcing today is composed of complex global projects managed by virtual teams and project variance. Outsourcing strategies and project variance leads to cost variation within a budget which usually is unaccounted for. Completing projects on budget can be achieved by managing four core domains: assumptions, your team, risk and the "system".

Planning and Forecasting

Planning is *goal* and *expectation* setting – the what, when and how work will be done. Effective and accurate planning is the first step towards successfully completing a project on a budget. Assumptions on units, resources, quality systems and technical requirements are often forecast by one party and left to another to deliver on; whether they are right or wrong. Knowledge management and early team involvement is a must.

The planning phase also includes risk management (any possible deviations) and communication planning. More specifically, planning should include what will be produced each hour, each week and each month. Teams focus better with clear and attainable project goals.

Controlling and Monitoring

Data Managers responsible for global, complex projects interface with many service providers or internal departments. The performance of these services, i.e. monitoring, can have a profound effect on the performance of a data management project, especially budget.



This part of Project Management requires proactive behavior. Project Managers should be able to answer the following questions: what will be measured? Why and how will we measure it? What are the results telling me?

Reporting & Communication

Communication is crucial to the building of relationships, close collaboration and high performance of many teams. Data Managers play a key role in any clinical project team and must effectively communicate their role in the 'system' to the wider team to reduce the effects that decisions made in the field will have on CDM downstream and for the benefit of their budget. Leadership and team management traits are a 'must have' for the 21st century data manager; keeping teams focused, efficient and motivated to preserve and maximise project budgets.

Reporting is just one part of communications. Well-defined reports must be goal-oriented and include metrics and risk. Reports need to be honest, accurate and analyzed. The results can allow for more innovation and proactive behavior.



Connection to Budget?

How can effective project management and teamwork affect the budget? Good team spirit increases motivation and enjoyment, and synergy will lead to innovative solutions. Open communication reduces the inertia afflicting projects. Overall, productive teams produce better outcomes:

- Only the team can achieve budget, not the individual
- Costing projects on past data is only a gauge

- Planning **how** the team will work is important
- Interpret data correctly: connect symptom to cause
- Create an environment of open reporting

Mark Campbell delivered this presentation at the ACDM (Association for Clinical Data Management) Conference in Brighton, UK in March 2011. He is presenting this presentation at the BIAS Annual Congress in Turin, Italy this month.

Eneide: Project Portfolio Management System



CROS NT has recently implemented the Eneide Project Management System to manage operations and business activities. The software was developed by ARITHMOS, CROS NT's IT branch, and is modelled on a typical project life cycle in a CRO from proposal development to project closure. Eneide offers a comprehensive set of business tools designed to enable organisations to manage contract development, resources, projects and operational plans. To learn more, visit http://www.arithmos.it/ppms_eneide.html.

CROS NT COMMUNICATIONS: CROS NT Becomes CDISC Gold Member

Lead by the Data Management department, CROS NT has contributed to the CDISC organization to provide Gold Member benefits to its employees.



At the end of April, CROS NT became a Clinical Data Interchange Standards Consortium (CDISC) Gold Member. The Gold Membership allows CROS NT employees access to the Members Only area of the CDISC website which includes member benefits.



CDISC is a "global, open, multidisciplinary, non-profit organization that has established standards to support the acquisition, exchange, submission and archive of clinical research data and metadata". Through the Gold Membership, CROS NT will have the following benefits:

- Access to new documentation for CDISC standards
- CDISC Case Studies and Business Cases
- Tools and presentations
- Access to new data standards and useful information

In the field of Clinical Data Management, CROS NT prides itself on its thorough understanding of industry trends and regulatory standards. In order to manage vast amounts of clinical trial data in an

efficient and cost effective manner, CROS NT relies on the CDISC data standards.

"As CDISC is a world-wide industry recognized standard and requested for FDA submissions, CROS has developed the knowledge and expertise to meet the CDISC requirements and at the same time satisfy Sponsors requirements by harmonizing reporting standards across studies and increasing efficiency and quality in the deliverables to Sponsors", says **Monica Pimazzoni**, Head of Clinical Data Management for CROS NT.

The CROS NT member profile can be found on the CDISC website: <http://www.cdisc.org/our-members>

CROS NT has many employees that are knowledgeable and well experienced in CDISC standards, including Statistical Programmers, **Matteo Ferrari** and **Giuseppe Di Monaco**. Read more about CROS NT's Clinical Data Management services and its implementation of CDISC by visiting the [website](#) or downloading the [Clinical DM Flyer](#).



CROS NT Lands Stateside

CROS NT has its sights set on expanding in the U.S. market. Last month, an American statistician joined CROS NT and the team is headed to the DIA Meeting in Chicago in June.

CROSS JOINS CROS NT

Last month, CROS NT welcomed an American-based statistical consultant to its team. **Amanda Cross** is based in Raleigh, North Carolina and has been a Data Services consultant for almost three years. Previously, Amanda has worked with Datatrial as Director of Business Operations and StatWorks as a Manager in Statistics. She is also a graduate of Virginia Tech University with a degree in Statistics.

What exactly is her take on the American market?

“The US Biotech industry has certainly struggled over the past few years, due to the economy. However, the outlook is promising and investment in these companies looks to be increasing again. There are always opportunities for companies like CROS NT to build relationships with biotechs and other small pharmaceutical companies. With the improvement of the economy, the time is right for CROS NT to build its presence in the US and establish these relationships”.

CROS NT EXHIBITING AT THE DIA MEETING IN CHICAGO

CROS NT is returning to the U.S. event circuit in 2011 with an exhibitor's booth at the DIA Annual Meeting in Chicago, Illinois June 19-22nd. This year, CROS NT hopes to expand its reputation in the American market by presenting its services and introducing some new consultancy services like the Statistical Scientific Board, a think tank for statistical methodology in clinical trials.

Representing CROS NT in Chicago will be CEO, **Paolo Morelli**, Vice President, **Frank Freishläger**, and Marketing Officer (and fellow American!), **Mary Wieder**.



CROS NT will be located at Booth #701. We invite you to stop by for information on our services, to meet our staff and enter our lottery for the chance to win a new iPod Touch. If you would like to schedule a meeting with us while in Chicago, please [send us an email!](#)

CROS NT SOCIAL MEDIA BANDWAGON



CROS NT has seen the need to incorporate social media into its communication plan. The United States has the second highest percentage of social media users next to China. European usage is highest in the UK and Germany – CROS NT's principal markets outside of Italy (see page 4 for our geographical breakdown).

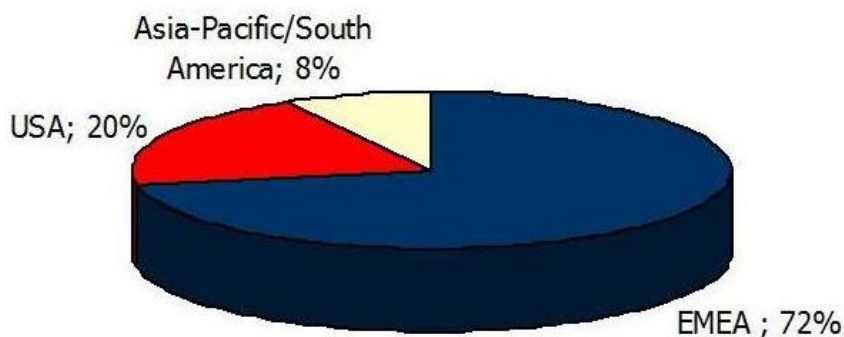
This year, CROS NT created its own [Facebook page](#) to post news and events as well as start a dialogue about events affecting the biopharmaceutical industry. CROS NT also has a [company page](#) on LinkedIn.

These social media outlets not only allow CROS NT to connect with its core business market, but also to communicate with its international colleagues.

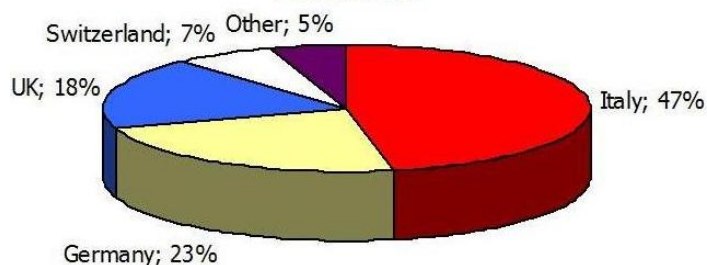
CROS NT: CROSSING BORDERS

Since its establishment in 1992, CROS NT has grown from a CRO based in Italy to an international CRO and Biotech group of companies operating worldwide. When CROS NT opened its German subsidiary, CROS DE, in 2010 it helped expand our reach throughout Europe. The graphs below show the international reach of CROS NT through clients, partnerships and business contacts.

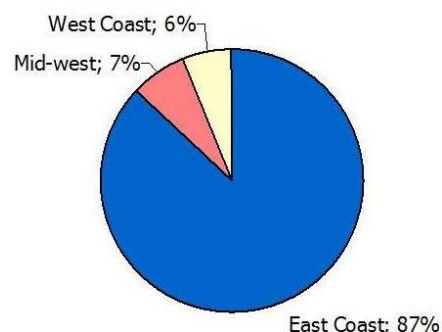
CROS NT Globally



CROS NT European Breakdown



CROS NT U.S. Breakdown



About the CROS NT Newsletter

The CROS NT newsletter is published bi-monthly alternatively with the ARITHMOS newsletter. The goal of the newsletter is to share relevant news and events from the biopharmaceutical sector and showcase work CROS NT has been doing in industry. Articles and content are produced in-house by CROS NT staff. You can find all of our newsletters archived on our website at <http://www.cros.it/newsletters>.

