
pmsquare
simplifying complexity

Clinical Trial Financial Management

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Presentation contents:

PMsquare Value Bombs

Clinical Trials Overview

PM^2CT: Clinical Trials Solution

IBM Partner status

IBM CHAMPION

Premier Business Partner

Authorized Software Value Plus

Healthcare

Premier Business Partner

Certified for IBM Business Analytics software

Certified for IBM Information Management software

IBM Certificate of Accreditation in Business Intelligence

Company Snapshot

Award winning PMsquare is the first accredited Business Analytics Business Partner in ASEAN and first Business Analytics Business Partner worldwide to achieve accreditations in multiple countries in which they operate.

Top verticals: Pharmaceuticals, Transportation, Retail, Manufacturing, Consumer Goods and Automotive.

Product capabilities: IBM Cognos BI, TM1, EP, SPSS, DataStage, Apparro Fast Edit.

Customer Summary:

- more than 50 clients;
- deployed in 20+ countries.

Locations: Singapore, Australia, USA, Philippines, Germany.

Our pharmaceutical clients:

SANOFI

SANOFI PASTEUR

What are Clinical Trials?

Clinical Drug/Device Investigation

A study of a drug (device, or diagnostic) where it

"…is administered or dispensed to, or used involving, one or more human subjects"

and is a

"prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical… interventions (drugs,... devices, or new ways of using known drugs… or devices)."

Translation:

"A drug or device intervention into a person".

Clinical Trials Focus

Clinical Trials are a business and must be run accordingly

A business best achieves goals by starting with a strategic plan

Clinical trials are conducted to collect data regarding the safety and efficacy of new drug and device development (Sponsor & Site)

Types of Clinical Trials

Pre Clinical Studies

If the initial laboratory research is successful, researchers send the data to the Food and Drug Administration (FDA) /EMA/Country Authority for approval to continue research and testing in humans.

Human Clinical Trial Phases

Phase I: Safety of a drug or device. Is it safe?

Phase II: Efficacy of a drug or device. Does it work?
30% or about one-third of experimental drugs successfully complete both Phase I and Phase II studies.

Phase III: Large Scale. Is it really safe/really works?
70-90% of studies that successfully complete it and request FDA Approval to market the drug.

Phase IV: Post Marketing Surveillance/Registries. What Else Do We Need to Know? Are there rare side effects not yet discovered? Are there risks associated with long-term exposure? These used to:

- compare a drug with other drugs already in the market;
- monitor a drug's long-term effectiveness and impact on a patient's quality of life;
- determine the cost-effectiveness of a drug therapy relative to other traditional and new therapies.

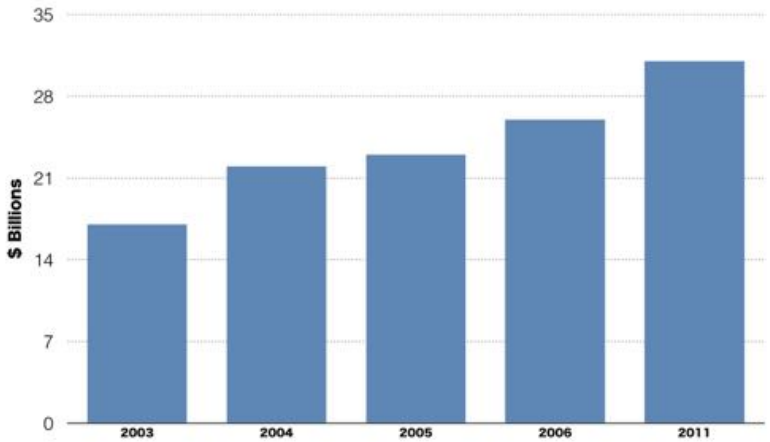
Phase IV studies can result in a drug or device being taken off the market or restrictions of use could be placed on the product depending on the findings in the study.

Clinical Trials Industry sponsored Statistics

Mainly Pharmaceutical and Biotech Companies

The term **Big Pharma** is often used to refer to companies with revenue in excess of $3B, and/or R&D expenditure in excess of $500M.

The annual investment in Clinical Trials is about $26B.



Sources: Wikipedia, Nature

Why managing Clinical Trials is Important

Studies published in 2003 report an average pre-tax cost of approximately $800 million to bring a new drug (i.e. a drug with a New Chemical Entity) to market.

A study published in 2006 estimates that costs vary from around 500 million to 2,000 million dollars depending on the therapy or the developing firm.

These figures relate only to new, innovative drugs. Each year, worldwide, only about 26 such drugs enter the market.

The development cost of the thousands of other drugs are much smaller. The $800 million quoted include the cost of all drug development which did not result in a new drug. It also includes some 400 million $ of opportunity costs.

…introducing PM^{2}CT powered by PMsquare

Sources: Wikipedia, Nature

PM²CT: Clinical Trials powered by PMsquare
…is a simple and powerful tool for:

- Optimizing Costs
- Ensuring accuracy of Clinical Studies estimation
- Dynamic allocation of resources
- Knowledge transfer
- Collaboration between Operations and Finance
- Internal Control and Data Management

PM²CT: Clinical Trials powered by PMsquare

PM²CT is a simple and powerful tool for Operational and Finance teams to:

Monitor costs for local and regional studies:

- Detailed costs information with latest references;
- Latest reference for Cost per Patient at country level;
- Consistent financial information across the globe.

Store clinical costs at different stages:

- Life Financial Management of Clinical Studies;
- Global & Country detailed information;
- Traceability of internal and official documents.

Access detailed information for Local and Global level:

- Anytime Anywhere —online, on your iPad or in Excel format.

Deliver operational excellence and mitigating internal control risks:

- Efficiency gain;
- Collaborative tool for Finance and non-Finance;
- Mitigate internal control risk.

PM²CT Key Roles in the System:

Global Study Controllers:

- what countries to choose for the study
- what-if scenario modeling
- phase costs top-down to estimate monthly costs per country
- monitor study execution across different countries

Country RnD Controllers:

- monitor all studies in the country
- upload actual cost and patient enrolment data from local systems

Project Leads/CTOMs/ CROs:

- track specific study in the country
- update rolling forecast
- track enrolment and contract invoicing

PM²CT Calculation Methodology

PM²CT Calculation Methodology combines two approaches:

Top-Down Phasing of Costs (mostly used on study planning phase) by:

- patient enrolment curve
- pro-rata phasing by study duration
- contract payment milestones

Bottom Up calculation for Rolling Forecast and Actuals to accurately track execution

PM²CT Calculation Methodology

PM²CT Costs Calculation includes:

Patient Costs, based on:

- patient enrolment
- procedures per visit
- overall study protocol to correctly calculate costs of follow up visits

Investigative and Comparative product pricing to accurately forecast:

- quantities required
- various buying and shipping costs

Contract-based Country Costs:

- Capture contract terms (duration and payment milestones)

Global Costs of running the Study:

- Capture the central cost of administering the study across different countries

PM²CT Reporting and Analysis:

- Real-time view of actual and forecast data
- Real-time consolidation of detailed data
- Multiple scenarios, what-if modeling
- Multiple currencies and exchange rate types (to compare scenarios excluding currency impact)
- Online dashboards and offline iPad reporting

PM²CT System Details:

- Single view of all the data;
- in-memory calculation engine (**IBM Cognos TM1**);
- All-encompassing reporting capabilities (**IBM Cognos Business Intelligence**)
- standard upload definitions to ease integration with the country systems;
- country controllers are responsible for the mapping of local chart of accounts and trial details to PM²CT master data;
- web-browser (**TM1 Contributor**) client with no installation required.

Thank you

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