Value Demonstration: Time & Motion Studies

Quantifying Increased Efficiency with Medical Interventions

Time and Motion (T&M) studies are observational studies designed to quantify efficiency-related outcomes associated with:

• The administration of medications, the use of medical devices, or the implementation of new technological processes
• The allocation of resources and time spent on healthcare delivery
• Patient flow through healthcare settings

Examples where efficiency benefits could be quantified through T&M include:

• Switches in drug formulation (e.g., from intravenous to subcutaneous or oral)
• Switches in standard of care (e.g., from physician administration to patient self-administration of drug)
• Advances in a technological process(es) resulting in faster data transmission and interpretation
Time and Motion Studies to Demonstrate the Value of Efficiency

To support product or medical device launch, do your data needs include evidence of efficiency?

T&M studies may offer you the right solution:

Innovative biopharmaceutical products, medical supplies or devices may show similar efficacy, effectiveness, and safety profiles compared to standard-of-care options. Their differentiating features, however, may be related to increased efficiency. This is of particular importance to payers, physicians, and patients when:

- T&M methodology consists of decomposing a treatment or care process into its main tasks, and designing a protocol and case report form to evaluate healthcare professional time spent on these tasks or patient time in a specific care setting
- T&M studies employ direct on-site observation by trained observers using manual timing techniques (e.g., stopwatches)
- Task durations are measured repeatedly and total treatment or process time is estimated through statistical analysis

An example of a T&M study conceptual framework in support of an intravenous-to-subcutaneous drug formulation switch is shown below:

**Time and Motion Studies – Why are they Useful?**

<table>
<thead>
<tr>
<th>Variables of Interest</th>
<th>Definition</th>
<th>Outcomes of Interest</th>
<th>Efficiency Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient time in treatment room</td>
<td>Time patient spends in treatment room</td>
<td>Patient time process 1 vs. 2</td>
<td>Patient time saved</td>
</tr>
<tr>
<td>Patient chair time</td>
<td>Time patient spends in infusion chair</td>
<td>Chair time process 1 vs. 2</td>
<td>Chair time saved</td>
</tr>
<tr>
<td>“Active” healthcare professional (HCP) time</td>
<td>Time “actively” spent by HCP on pre-defined tasks</td>
<td>HCP time process #1</td>
<td>HCP time saved</td>
</tr>
<tr>
<td>HCP time process #2</td>
<td></td>
<td>HCP time process #2</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Consumables avoided/saved</td>
<td>Long-term cost impact (opportunity cost)</td>
</tr>
</tbody>
</table>

- Resource savings
- Increased throughput
- Short-term cash flow impact
Tailored Evidence for a Diversity of Stakeholders

Unlocking the value of treatment or care process efficiency is particularly important with the cost constraints of the current healthcare environment. Diverse stakeholder groups — payers, physicians, and patients — each require real-world evidence of value specific to their decision-making needs.

<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>Value of Efficiency and Evidence Needs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient</td>
<td>• Reduction in travel, waiting, and treatment times&lt;br&gt;• Opportunity cost of treatment or process time in local currency</td>
</tr>
<tr>
<td>Healthcare Professional (HCP)</td>
<td>• Reduction in “active” HCP time&lt;br&gt;• Opportunity cost of time saved (in local currency)&lt;br&gt;• Volume of additional patients treated and population health benefits</td>
</tr>
<tr>
<td>Hospital Administrator</td>
<td>• Increased healthcare facility capacity&lt;br&gt;• Hours of HCP time freed up&lt;br&gt;• Reduction in waiting lists</td>
</tr>
<tr>
<td>Payer</td>
<td>• Fee-for-service payment for additional patients treated&lt;br&gt;• Total funding under different treatment scenarios&lt;br&gt;• Opportunity cost of facility usage (in local currency)</td>
</tr>
<tr>
<td>Government</td>
<td>• Overall efficiency of health service&lt;br&gt;• Volume of additional patients treated&lt;br&gt;• Productivity of population</td>
</tr>
</tbody>
</table>

Efficiency Gains Translated into Economic Value Messages

Outputs from T&M studies can be used to generate quantitative economic value messages that highlight the monetary value of:
• Healthcare professional time saved
• Increased healthcare facility usage and capacity
• Decreased burden and increased patient productivity as a result of faster treatment or care process time

T&M STUDY OUTPUTS
- Time spent by:
  - Patients
  - Healthcare staff
  - Process duration
  - Resource utilization
  - Supplies consumed

ANALYTICAL APPROACHES
- Micro-costing
- Activity-based costing
- Facility efficiency modeling
- Patient throughput modeling
- Cost-effectiveness analysis
- Cost-minimization analysis
- Budget impact modeling

VALUE MESSAGES
- Evidence of:
  - Savings in costs
  - Savings in time for patient and healthcare provider
  - Increased treatment volume, facility throughput, and associated revenues
  - Treatment or care process satisfaction
UBC Approach

Robust Methodology
Step-wise approach to the conceptualization, design, and conduct of scientifically robust and operationally feasible T&M studies:
• Articulation of clear research objectives
• Identification and resolution of key methodological considerations:
  • Analytical versus descriptive design
  • Sources of variability (e.g., between countries, between centers)
  • Sources of confounding from patient or process-related characteristics
  • Sample size
• “Mapping” of routine care patterns with the aim of defining T&M variables of interest
• Rapid site feasibility assessments of the basic requirements for participation
• Deep understanding of regulatory requirements across Europe and the Americas for non-interventional studies that focus on T&M-type outcomes as opposed to traditional patient-based outcomes

Strategic Consulting Services
• UBC engages in constructive discussions regarding the optimal design for the collection of “efficiency” data, as well as methods to integrate T&M outcomes within existing interventional study designs
• UBC often runs single-center “pilot” studies to inform the usefulness of a multi-center design
• Collection of T&M endpoints can be combined with chart data abstraction of study treatment patterns or patient/HCP questionnaires on treatment satisfaction, preference, and quality of life

Unparalleled Experience
• UBC has designed and executed Time & Motion studies in more than 20 countries across Europe and North and South America
• The scale of these studies has varied from 1 to 35 design-and-execution sites
• Sample sizes have varied from fewer than 20 to 1000+ process observations
Quantification of the Impact of Increased Efficiency on Patient Outcomes and Healthcare Delivery

*Blue indicates UBC Scientist.

Selected Recent Publications

**De Cock E, Dellana F, Khellaf K, Klatko W, Maduell F, Raluy M, Vila Giuseppe.**

**Schiller B, Doss S, De Cock E, Del Aguila MA, Nissenson AR.**

**Payne KA, Yeomans K, De Cock E.**

**Saueressig U, Kwan, J TC, De Cock E, Sapede C.**

**De Cock E.**
Time and Motion Studies to Quantify the Real-world Impact and Value of Medical Devices – from Design Concept to Dissemination. *NextLevel Medical Device Commercial Leaders Forum; June 10-11, 2014; Chicago.*

**De Cock E.**
Time and Motion Studies for Building Economic Value Messages - Conceptualization to Dissemination. *CBI Annual Late Phase Research EU; May 22-23, 2014; Dublin.*

**De Cock E.**
Time and Motion Studies for Measuring Efficiency-related Outcomes – Opportunities and Challenges. *CBI Late Phase Research/Real-World Data Conference; March 6-8, 2013; Amsterdam.*

**De Cock E., Tao S, Urspruch A, Knoop A.**
Potential time savings with trastuzumab subcutaneous (SC) injection vs. trastuzumab intravenous (IV) infusion: results from interviews conducted as part of a time-and-motion study (T&M) across 17 sites. *ISPOR 15th Annual European Congress; 3-7 November 2012; ICC Berlin, Berlin.*
Selected Recent Posters

*Blue indicates UBC Scientist.

Kritikou P, De Cock E.
Quantifying the efficiency of health care interventions: a review of time and motion studies presented at ISPOR conferences between 2008 and 2013.
ISPOR 19th Annual International Meeting, May 31 - June 4, 2014; Montreal.

Yeomans K, Payne KA, Blume SW, Tao S, Hubbard SM, Allen-Ramey F.
Hybrid time and motion, patient survey and chart review study methodology: a case study of subcutaneous allergen immunotherapy in the US and Canada.
ISPOR 19th Annual International Meeting, May 31 - June 4, 2014; Montreal.

De Cock E, Kritikou P, Tao S, Wiesner C, Waterboer T, Carella AM.
Time Savings with Rituximab Subcutaneous (SC) Injection vs Rituximab Intravenous (IV) Infusion: Final Analysis from a Time-and-Motion Study in 8 Countries.
American Society for Hematology Congress; December 7-10, 2013; New Orleans.

De Cock E, Tao S, Desrosiers M-P, Millar D, Califaretti N.
Time savings with trastuzumab subcutaneous (SC) injection vs. trastuzumab intravenous (IV) infusion: a time and motion study in 5 Canadian Centres.
Canadian Association for Population Therapeutics (CAPT) Annual Conference; November 17-19, 2013; Toronto.

Kritikou P, De Cock E, Proskorovsky I, Payne KA, Tomic R.
Handling variability in time endpoints in multi-centre Time and Motion (T&M) Studies: a case study of erythropoiesis-stimulating agents for anaemia management in 13 Centres in Italy.
ISPOR 16th Annual European Congress; November 2–6, 2013; Dublin.

Kritikou P, Bassel M, De Cock E, Payne KA.
ISPOR 16th Annual European Congress; November 2–6, 2013; Dublin.

European Cancer Congress 2013 (ECCO-ESMO-ESTRO); 27 September - 1 October 2013; Amsterdam.

Yeomans K, Payne KA, Pan YI, De Cock E.
Time and Motion study Design: Handling Variability and Confounding of results.
ISPOR 18th Annual International Meeting; May 18-22, 2013; New Orleans.

De Cock E, Payne KA, Urspruch A.
Design and operational challenges with Time and Motion (T&M) studies run alongside clinical trials.
ISPOR 17th Annual International Meeting; June 2-6, 2012; Washington, DC.

De Cock E, Van Nooten F, Raluy M, Muller K, Fabre J, Hargreaves J.
Time and Supplies for Wound Management during and after Breast Reduction Surgery in Germany and The Netherlands: Prineo® vs. Standard of Care.

De Cock E, Van Nooten F, Raluy M, Muller K, Fabre J, Hargreaves J.