

## The Opportunity

Medtronic engaged Motive Power in the creation and implementation of a globally standardized clinical research study management process (SSMP) and harmonized standard operating procedures (SOP) following its acquisition of Covidien.

Medtronic's goal was to optimize operational efficiency and cost savings and to increase data quality across its global clinical research organization.

Medtronic trusted Motive Power with this implementation based on proven past performance and results.

## The Plan

Motive Power's four-phase plan was built around involving Medtronic stakeholders from each organization throughout the entire program. All 18 organizations and more than 1,800 people were engaged globally in a comprehensive change management program, including focus groups, training design and facilitation for 97% of the clinical research organization, a multi-tiered communication strategy and a change agent program. The program also included process design in partnership with focus groups, iterative subject matter expert input to training materials design, and targeted change support tactics. Motive Power managed the implementation, acting as a partner and trusted advisor to the client team.

Start: May 1, 2016

Finish: September 30, 2016

Budget: \$2.6M

## Phase 1

### SSMP Development (Jul 2015)

Motive Power partnered extensively with Medtronic to develop the SSMP, involving the Operations Sub-Council (OSC) and more than 125 focus group members representing the global organization in the creation of a process which could provide global guidance to each business unit, regional group and functional group. This plan was implemented in collaboration with Halloran, a partner firm who also engaged subject matter experts within the clinical organization to write harmonized SOPs in support of the SSMP. Based on the approved standard study management process design, Motive Power also partnered with the client IT team to design and deploy a centralized, interactive one-stop-shop software application where clinical employees would access the process, SOPs and business efficiency tools to perform clinical research study management in the future state.

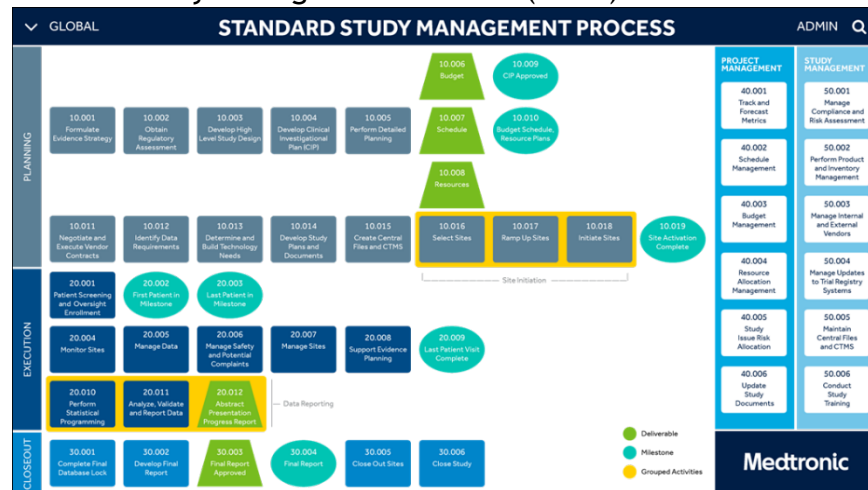
## Change Management Practices

Global Standardization:

1. Align influencers and decision makers with project goals by consistently engaging them and gathering input via focus groups.
2. Facilitate constant evaluation and iteration of training materials throughout deployment via SME and training participant input.
3. Produce actionable Adoption Metrics to highlight any project risks or issues and allow for early actions

During this phase, Motive Power also developed and began deployment of a comprehensive communication plan that identified audience segments and tailored information for distribution within each organization on a measured timeline

## Standard Study Management Process (SSMP) in Clinical Connect



## Phase 2

### Deployment Plan Development (Aug - Dec 2015)

After the SSMP and the SOPs were approved by the OSC, Motive Power turned its attention to developing a deployment plan for the SSMP and SOPs. These new governing documents became the substance of training delivered by Motive Power to more than 1,800 employees, in nine countries, in a 22-week period.

To tackle this challenge, focus groups were established for each of the 18 global organizations. Each focus group was led by a Motive Power lead and a regional client leader or member of the Operations Sub-Council. This established client accountability and facilitated efficient client input and decision making. Three Motive Power employees each led six of the 18 groups. Focus groups met bi-weekly for two hours at a time. This consistent meeting time also allowed strong relationships to develop organically between Motive Power and client organizational leaders.

Motive Power also identified Subject Matter Experts (SMEs) to review training materials and provide guidance and credibility in each training delivery. The SMEs helped deliver training via both in-person presentations and pre-recorded videos which were incorporated to training materials.

Motive Power also partnered with focus groups and the OSC during this phase to design a deployment plan which would optimize the client budget, delivering training with minimum client travel expense and maximum face time among members of each clinical organization. Motive Power also delivered three pilot training sessions in two locations to tailor and begin iterative improvement of training content design.

## Phase 3

### Deployment (Jan - Jun 2016)

Motive Power deployed eight trainers over 22 weeks to deliver SSMP and SOP training to the Medtronic clinical organization. Each training was supported by two to five trainers, according to the size of the training group, which ranged from 15-150 Medtronic employees. Motive Power's training design and facilitation performance was measured by surveys distributed at the end of the 2.5 day training sessions. Motive Power partnered with the client to make iterative adjustments to the training materials throughout deployment, which resulted in steadily improved scores and left the client happy and supportive of our work.

Adoption support continued after training deployment with a program called Hypercare, which provided an elevated level of support throughout deployment through targeted topic webinars, an actively maintained support email address and open office hours. Motive Power also shifted stakeholder focus group engagement to clinical tracked site team engagement to minimize client resource demand and to position the organization to drive results through its existing quality control function.

## Phase 4

### Adoption (Jul - Sep 2016)

Motive Power drove adoption and transition of all studies, tracked sites, and business units through the creation of Adoption Metrics. Adoption Metrics were automated to the extent possible to ensure the team could allocate focus to follow-on discussion and actions to guide and reinforce organizational adoption. The Adoption Metrics were produced bi-weekly to highlight actionable risks and issues to support their pro-active management and to drive the team to on-time completion of required SSMP and SOP transition activities. Additionally, the Motive Power team met one-on-one with key stakeholders and organizational leaders within each business unit and clinical tracked site to review the data and create actions plans which addressed any identified deficiencies. Motive Power also continued to partner with client Tracked Sites to provide key messages and transition activity guidance to all study teams as they planned for and completed transition activities prior to the November 1, 2016 deadline.

Action Required	APV	CRUI/AF	CSH	Diabetes	Insp	MTG - ET	MTG - PAM	MTG - ST	Neuroend	Neurovasc	PAN	Spline	ST	RCS
95% of clinical employees have completed face to face training														
Governance process in place for CC tool linking														
Content Administrator assigned														
Organizational specific efficiency tools have been linked and old documents archived														
All STAPs submitted														
No Past Due Study Transitions														
Monitor High Risk Study Transitions and Study Closures														
Organizational Training Matrix submitted														
Quality System changes have been executed														