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Clinical Research Program Manager

Orthopedic Medical Devices • Biotechnology • Cardiovascular

Expedited FDA approval by five months

Cut clinical trial costs 18%

Reduced patient attrition 32%

Global research trailblazer who has created protocols, managed clinical trials, launched new programs, built clinical teams, and orchestrated projects to fast-track approval.

- Global Clinical Trial Management: Drove all stages of 68 clinical trials, meeting milestones and accelerating timelines through critical path analysis.
- **Compliance:** Deep knowledge of FDA and CE regulations, ICH-GCP guidelines, and good documentation practices (GDP).
- Clinical Staff Recruitment: Hired and trained 27 talented physicians to oversee investigations.
- Data Integrity: Created processes that ensured the accuracy, quality, and confidentiality of trial data.

Research and Development
Trial Protocol Design
Clinical Monitoring
ICH-GCP Guidelines
FDA and CE Mark Compliance
Documentation (GDP)
Quality Assurance (QA/QC)
Budget Management
Clinical Staff Supervision
New Program Launch

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PROFESSIONAL EXPERIENCE

RZ MEDTECH | Minneapolis, Minnesota | A \$7.9B medical device company; global leader in musculoskeletal healthcare.

Clinical Study Manager (5/2018—Present)

Promoted to lead global clinical trials of orthopedic devices across nine study sites. Develop trial protocols and clinical monitoring plans. Recruit and train surgeons to oversee investigations. Track enrollment, metrics, and milestones. Control project budgets. Ensure adherence to SOPs and GCP.

Challenge: To overcome a 36% patient dropout rate and expedite approval despite previously high patient attrition.

- Lowered patient dropout rate 32% by designing a new trial protocol and patient communication system that reduced attrition from 36% to 24% well below national average.
- Won FDA approval an unprecedented five months ahead of schedule for a first-of-its-kind hip device, enabling a rapid go-to-market strategy.
- Reduced trial expenses 18% without compromising quality or timelines.

Attrition Before



■ Dropout ■ Retained

Attrition After



■ Dropout ■ Retained



RZ MEDTECH BIO | Minneapolis, Minnesota | An \$820M subsidiary of RZ that specializes in biotechnology research.

Clinical Evidence Supervisor (9/2016—5/2018)

Researched and analyzed industry developments to support biotechnology teams. Managed a comprehensive internal database and disseminated 12,000+ international scientific publications.

- Authored and won nine European medical facility bids on tight timelines.
- Wrote 109 clinical summaries that provided a foundation for bids and marketing content.
- Developed a report to support market entry of a blood rejuvenation biotechnology product.
- **Designed new and more efficient SOPs** for reviewing published medical studies and compiling them in a library database enabling faster access to current data.

HOPEWELL HEALTH | Grand Rapids, Michigan | An integrated, non-profit health system with 456 locations in the Midwest.

Supervisor, Cardiovascular Research Operations (1/2009—9/2016)

Tapped by the Medical Director of Cardiology to co-create a new research program and manage research operations. Supervised a team of 20+ cardiologists, nurses, medical students, and technicians. Managed a budget of \$2.8M. Compiled research data and created monthly reports. Ensured compliance with clinical trial protocols and federal regulations.

Challenge: To establish Hopewell's *first* cardiovascular research program.

Co-launched a new program that positioned Hopewell as a recognized leader in cardiovascular research.

- Established strategic direction and vision to maintain a diversified portfolio of studies.
- Collaborated with cardiovascular physician investigators to develop clinical trials.
- Orchestrated 50 clinical research projects, including C-Valve, CAVR Low Risk, and H-TMVR.
- Recruited and trained a clinical research team of 20.



EDUCATION EDUCATION

PURDUE UNIVERSITY, Indiana
Master of Business Administration (MBA)
Bachelor of Applied Sciences in Health Sciences (B.AS.)

CERTIFICATIONS & MEMBERSHIPS



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Certified Clinical Research Professional (CCRP)
CRA Accreditation, Barnett International
Good Clinical Practices (GCP) ICH Certified | NIH CERT Training
CITI Program, Human Subject Protection Program

₹ TECHNOLOGY

Microsoft Office: Word, Excel, PowerPoint, MS Project, MS Access Research Compliance Software: IRB Manager Trello, CTMS, EDS, eTMF



Project Strategy

Background

Tara's career in clinical program management began after a brief stint as a practice manager for a hospital cardiologist. When he asked her to help him establish a new research program, she was thrilled. They codeveloped a program that put their hospital on the map for cardiology research.

Tara later joined a large biotechnology and medical device company, where she continued her career in clinical research management. After eight years with RZ, Tara was hearing rumors of possible layoffs. While she loved her current role, she wanted to be prepared with a high-impact resume.

Design

For the banner, I selected and licensed an existing image, but heavily customized it for Tara. First, I created a large white circle for her name and related certifications. I added a line to attach the large circle to a smaller one and unify it with the rest of the banner. The image included smaller circles with medical icons – but only about half of these were relevant to Tara's areas of expertise (biotech, orthopedic, and cardiology.) To remedy this, I customized the image by designing more relevant icons to replace the ones that were not relevant.

I tied this design into the remainder of the document by adding icons resembling chemical formulas to each section header. To further unify the design, I created a white circle with the hexagon icon for the page header, and a white circle for the page numbers in the footer.

Summary

At the top of the summary, below the headline and clinical areas, I summarized three of Tara's primary accomplishments: Expedited FDA approval by five months, cut clinical trial costs 18%, and reduced patient attrition 32%. Front-loading her key accomplishments ensured they wouldn't be overlooked.

Experience

In two of Tara's positions, there was a primary challenge that helped set the stage and tell her story. I highlighted each challenge in aqua, then bulleted the accomplishments and results.

In her current position, I created two doughnut-style graphs to illustrate the reduction in attrition. This led to her success in expediting the study and obtaining FDA approval five months ahead of schedule. (24% attrition may sound high, but it is well below the national average of 30%.)

For her Hopewell position, I designed an award logo to demonstrate that the new program put Hopewell on the map as a leader in cardiology research. Although I fictionalized the logo to protect confidentiality, the national recognition was real.

Outcome

Fortunately, Tara was not laid off from her current company. In fact, when she supplied her employer with an updated resume, she received a raise!