

Contextual Inquiry: Experience-Based Best Practices

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Abstract

As the medical industry continues to evolve and become increasingly user-centric, research methodologies such as Contextual Inquiry (CI) have garnered interest from medical device manufacturers. However, many interested human factors (HF) practitioners and medical device manufacturers are inexperienced with CI and may benefit from experience-based guidance beyond that found in industry standards^{1,2,3,4}. This poster summarizes CI best practices drawn from the unique experience BlackHägen has carrying out CI endeavors.

Introduction

What is Contextual Inquiry?

- Contextual Inquiry is the “process of observing and working with users in their normal environment to better understand the tasks they do and their workflow.”².
- Oftentimes, this type of research is most beneficial at the beginning of a product development project to establish product requirements and inform user needs; but CI may also be leveraged after product release to gauge real-world usability and generate feedback for future revisions (post market surveillance).

What can Contextual Inquiry be used for?

- Contextual Inquiry is one method in which researchers can gather an “up-front analysis of user needs”² that might not be adequately represented in simulated-use studies.
- Contextual Inquiry may also help define and characterize the device’s real-world users. These identified user groups may be emulated during formative and summative/validation usability testing.

How do I conduct a Contextual Inquiry study?

- Contextual Inquiry studies typically develop through four main stages: Preparation, Observation, Data Analysis, and Data Delivery.
- Additional detail and sub-activities will be given to these four stages.

Preparation

Set Expectations

- Study goals should be set early on. Contextual Inquiry can investigate new product opportunities, evaluate existing product performance, and/or set VOC needs for future devices.
- Are there any known issues within the specific product space? Existing problems can help define an investigative path for the research.
- Understand client/organization expectations for study output. For example, is video data required?

Establish Study Documentation

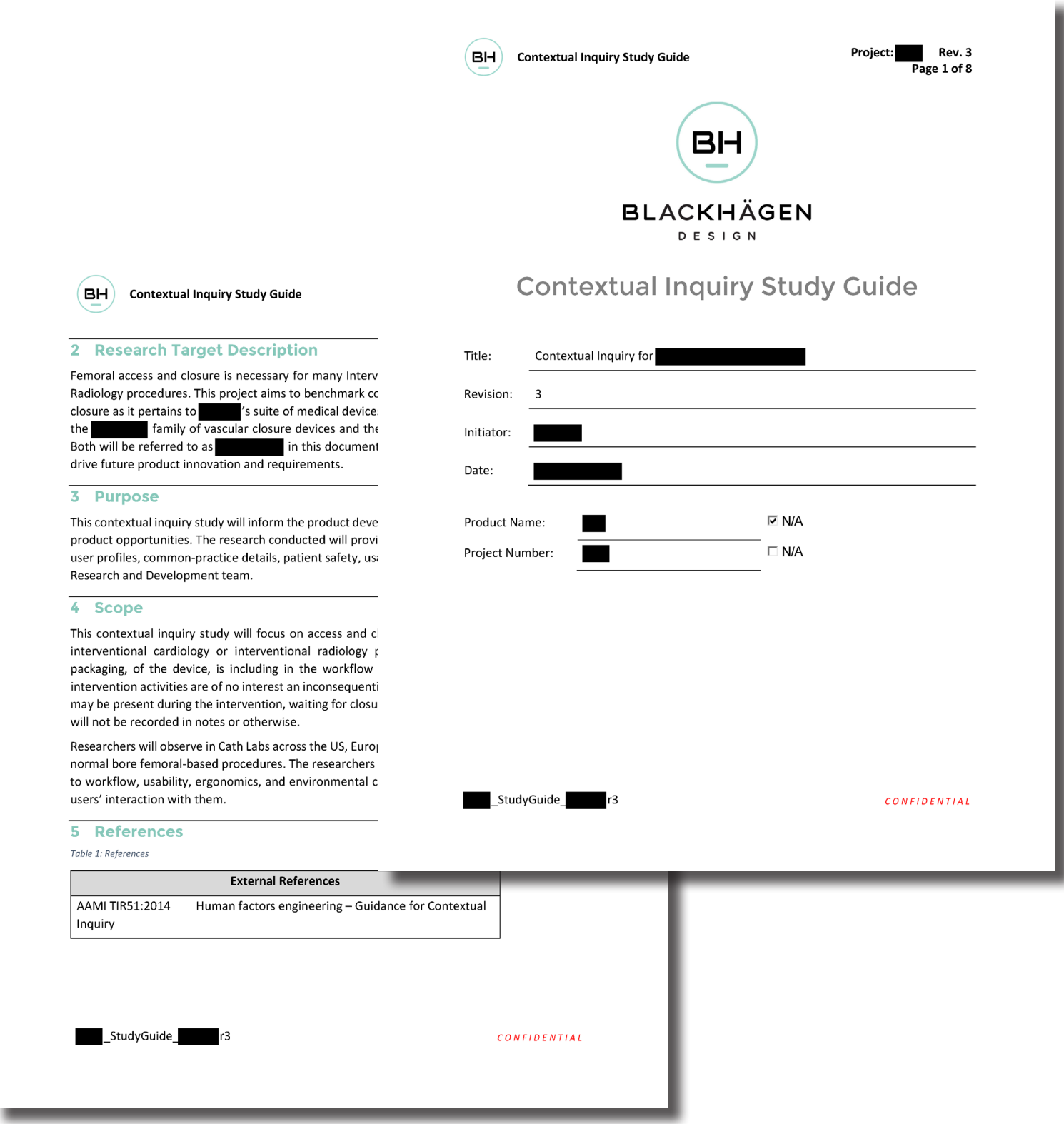
- Certain pieces of documentation (e.g. study guide, consent forms, etc.) may be helpful to prepare early on, before contacting study sites.
- To gain access to study locations, oftentimes your point of contact (POC) will want additional detail on your study.
- Depending on the type of procedure you want to observe or the specific institution you’re trying to gain access to, sometimes an IRB submission packet will be required as well.
- Prepare a brief exec summary of study guide, “Elevator Pitch.”

Establish Study Sites

- Depending on the availability of the desired product use or procedure type, study sites may be established by convenience sampling or by a more selective approach.

Establish Study Sites (Continued)

- The client/organization may already have contracts in place with certain institutions or clinicians; these can be leveraged into easy points of contact for the research.
- Oftentimes, it is important to rely on vendor reps to make introductions and guide the clinician interaction early on.
- Every hospital has protocols unique to them. If you do gain approval, the hospital may still bar certain parts of your observation (e.g. video recording).
- Researchers will need to pass credentialing for each institution (e.g. current vaccination records, completion of online learning, etc.).



Observation

What should you focus on during observations and how should you conduct yourself within the clinical environment?

Observational Footprint

- When observing, remember that *you are a guest*. Strive to take up as little space as possible and be ever conscious of what is going on around you.
- Avoid interrupting the clinicians’ workflow by getting in the way or contaminating the sterile space (this will get you expelled).

Observational Focus

- What tools are the clinicians using? Are those tools intended for that use?
- What types/quantity of users are involved?
- What steps do users typically employ?
 - Are they following the indicated use of the product(s)?
 - Are they employing any work-arounds?
- Do you notice any difficulties or frustration from the users?
- Look for post-it notes that explain a design deficiency, pauses or additional time examine device or system in order to understand operation.



Data Analysis

Data processing is an important step in CI methodology in order to produce deliverables that meet client/organizational expectations. There are several modes of analysis that may come into play.

Video Processing

- Video gathered during observations may benefit from processing with tools like Adobe Premier Pro or After Effects.
 - Multiple synchronized video feeds - picture-in-picture can provide viewers with a more complete picture.
 - It may be necessary to blur faces before releasing the video to viewers.
- Video data can allow researchers to add a time-motion aspect to the CI. By tracking the time it takes to perform certain tasks, researchers can evaluate the effects of certain factors.

Non-observational Data

- Additional data may be gathered that is not strictly observational.
 - Interview data is a common supplement to contextual inquiry.
 - Interview data should typically be gathered outside the scope of the users’ workflow (e.g. between surgeries) so as to not interrupt or bias the observational data.

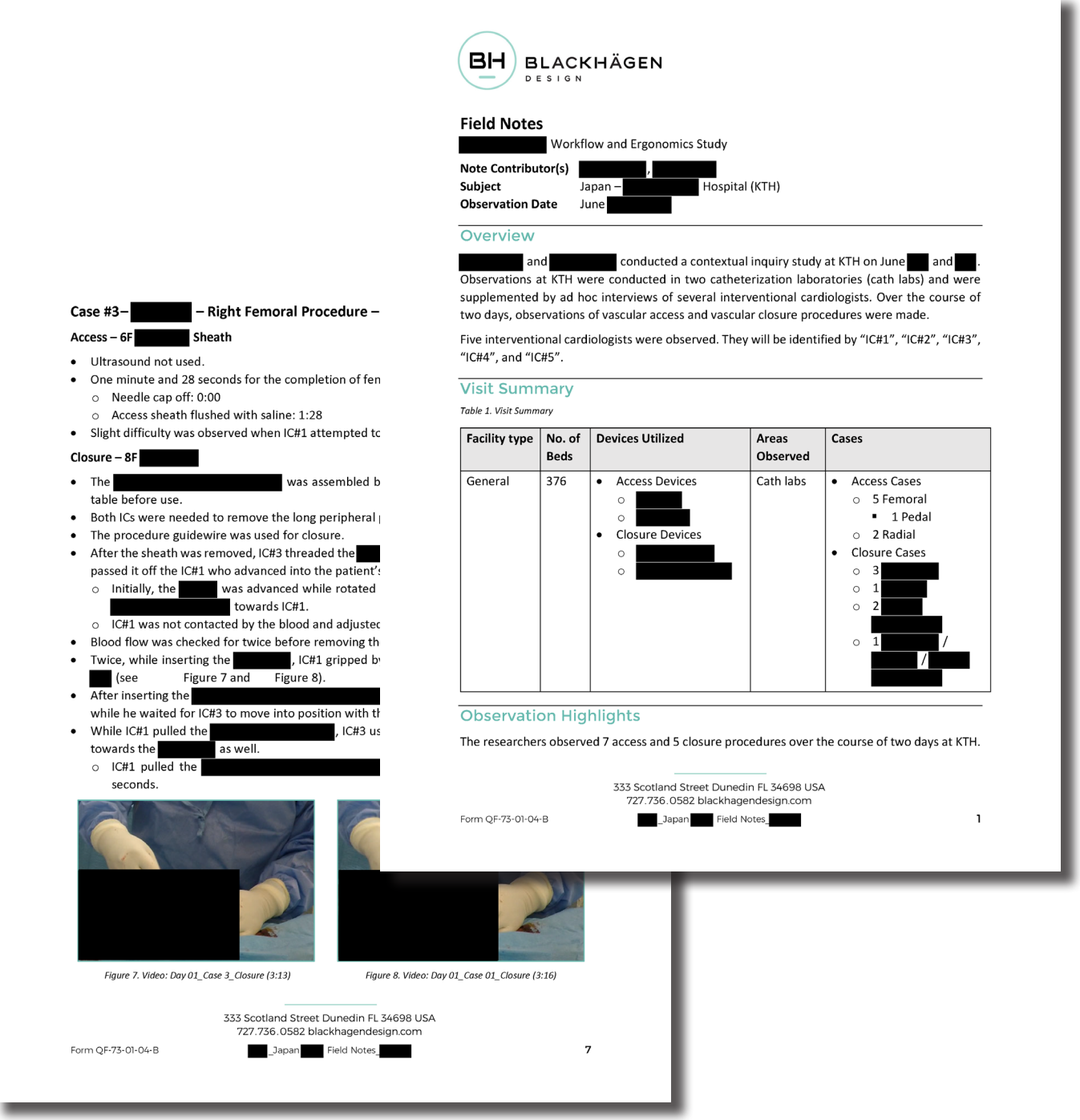
Example Surgical Layout

- The figure below is an example of an operating room CI study.
- Observers are standing out of the way, and have placed their cameras to capture the surgical site as well as the general workflow of the room.
- The surgical site camera is focused on the primary user’s tasks, the 2nd camera is focused on the team workflow.

Data Analysis (Continued)

Aggregate Data Sheet

- As the study develops, it may be helpful to create a place to aggregate all the collected data.
- An aggregate data sheet helps to delineate the potentially varied data into greater categories or trend groups.
- Ultimately, the aggregate data sheet may be leveraged to help generate the project’s final deliverables.



Data Delivery

A number of deliverables may be appropriate for a medical device contextual inquiry study depending on the device, the context of use, and the goals of the research endeavour.

Field Report(s)

- While they are a valuable tool for early analysis, field reports may also serve as a deliverable.

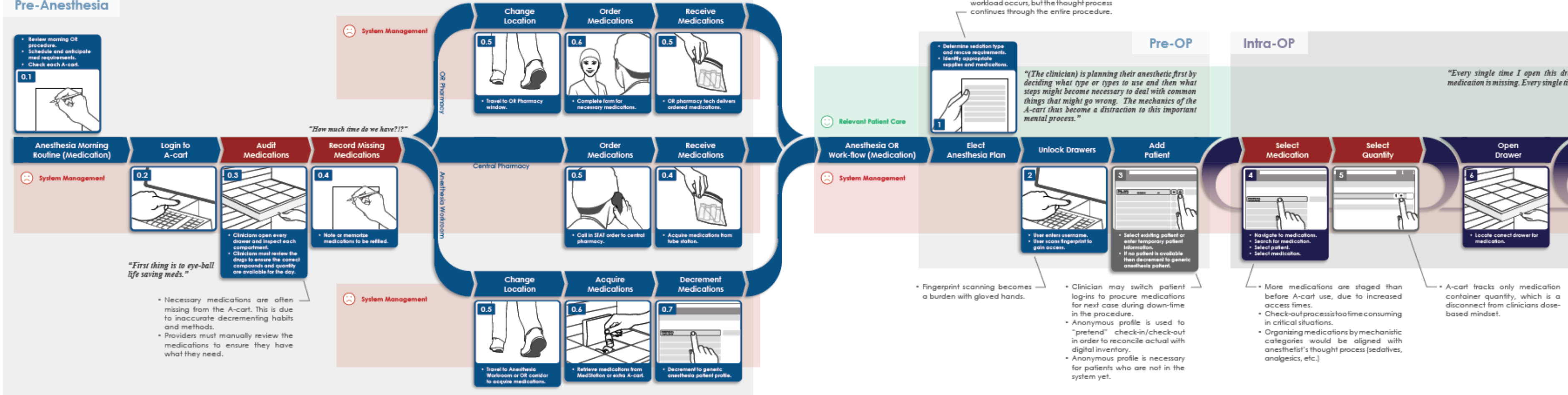
Procedure Map

- A procedure or process map can be generated for workflows that follow a set pattern of steps.
- Each task can be evaluated for strengths and weaknesses based on insights from the research.
- Time metrics can also add an additional element to this type of deliverable.

Synthesis/Workshop

- After the successful completion of a contextual inquiry project, one way to generate solid action items is to bring together project stakeholders for a synthesis workshop.
- The teams can review the insights and, through iterative brainstorming sessions generate user needs and requirements priorities for further development of the product plan platform.

OR Workflow



References

1. AAMI/IEC (2016). TIR62366-2, *Medical devices – Part 2: Guidance on the application of usability engineering to medical devices*. June 2016

2. ANSI/AAMI (2009). HE75, *Human factors engineering - Design of medical devices*, October 2009

3. FDA (2016). *Applying Human Factors and Usability Engineering to Medical Devices*, Guidance for Industry and FDA, February 2016

4. AAMI (2014). TIR51, *Guidance for Contextual Inquiry*

Intrinsic Expertise

- BlackHägen Design has completed hundreds of generative research studies for medical devices within U.S. healthcare institutions and homes. By completing contextual inquiry endeavours within a wide variety of environments, BH has intrinsic knowledge and skills applicable to the development and execution of the CI methodology.

