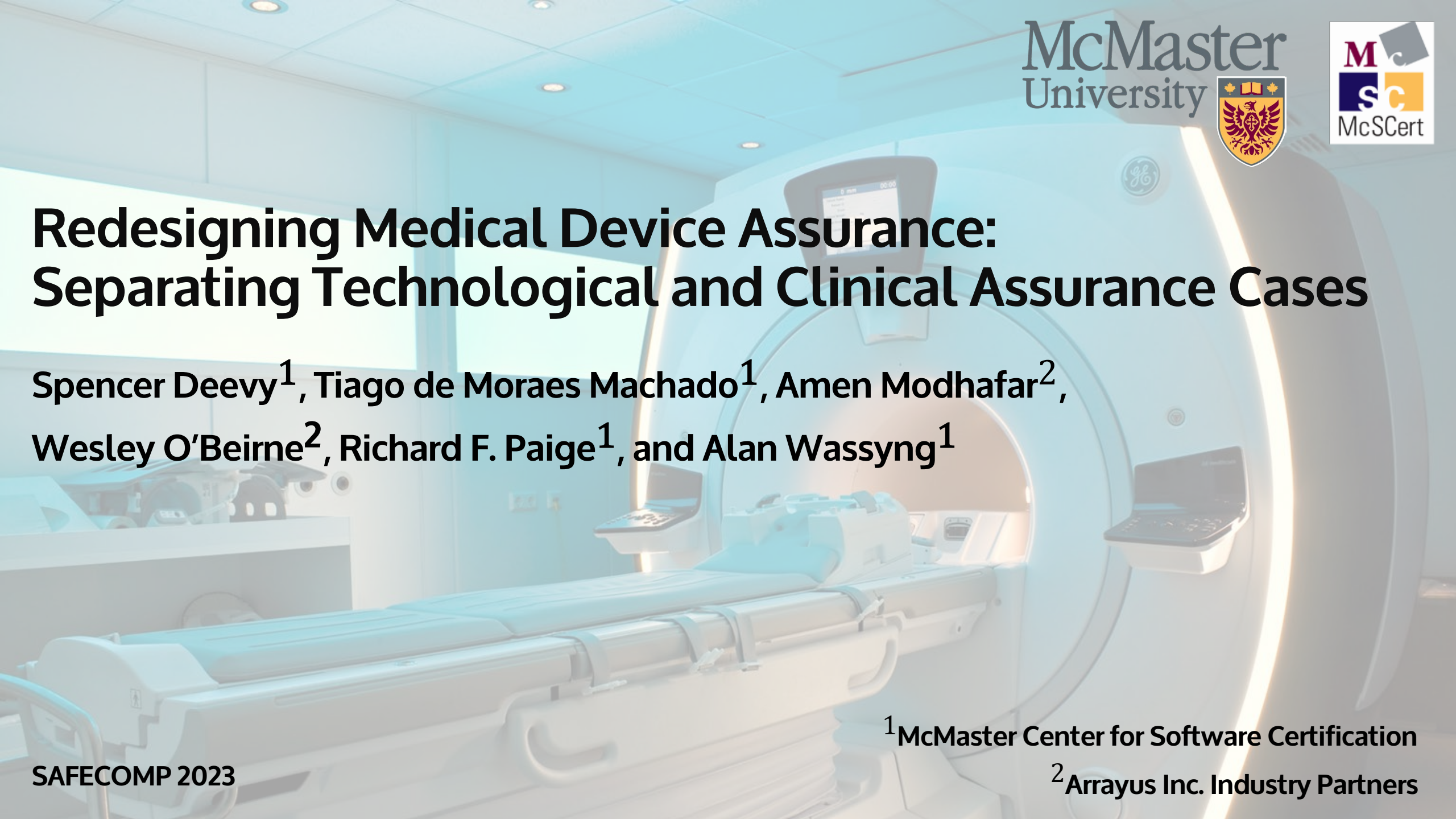

Redesigning Medical Device Assurance: Separating Technological and Clinical Assurance Cases

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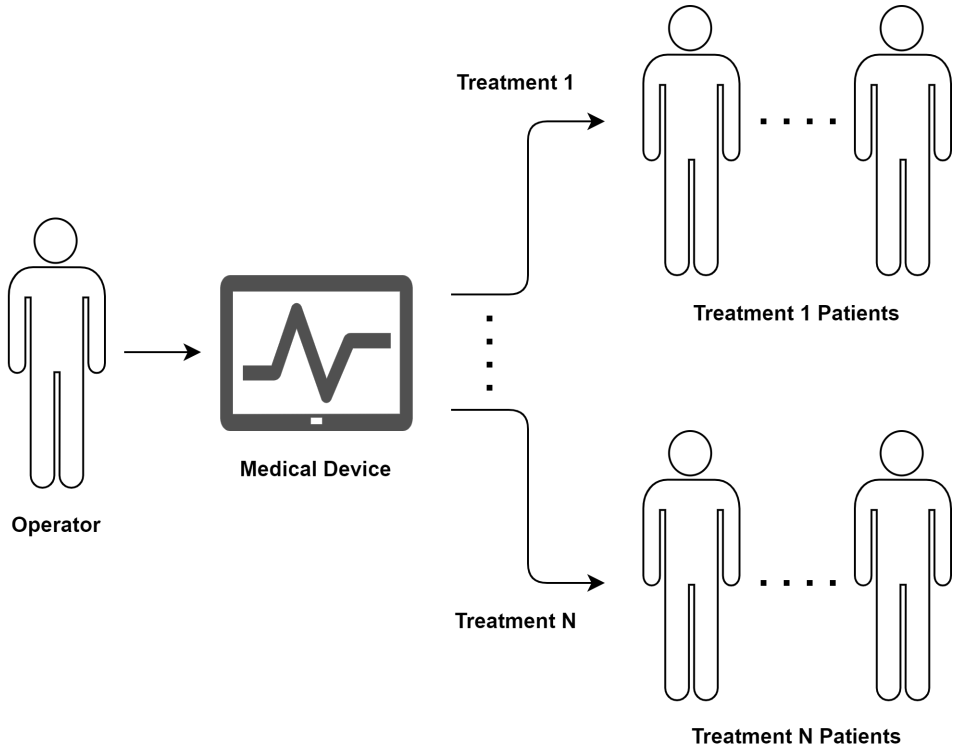
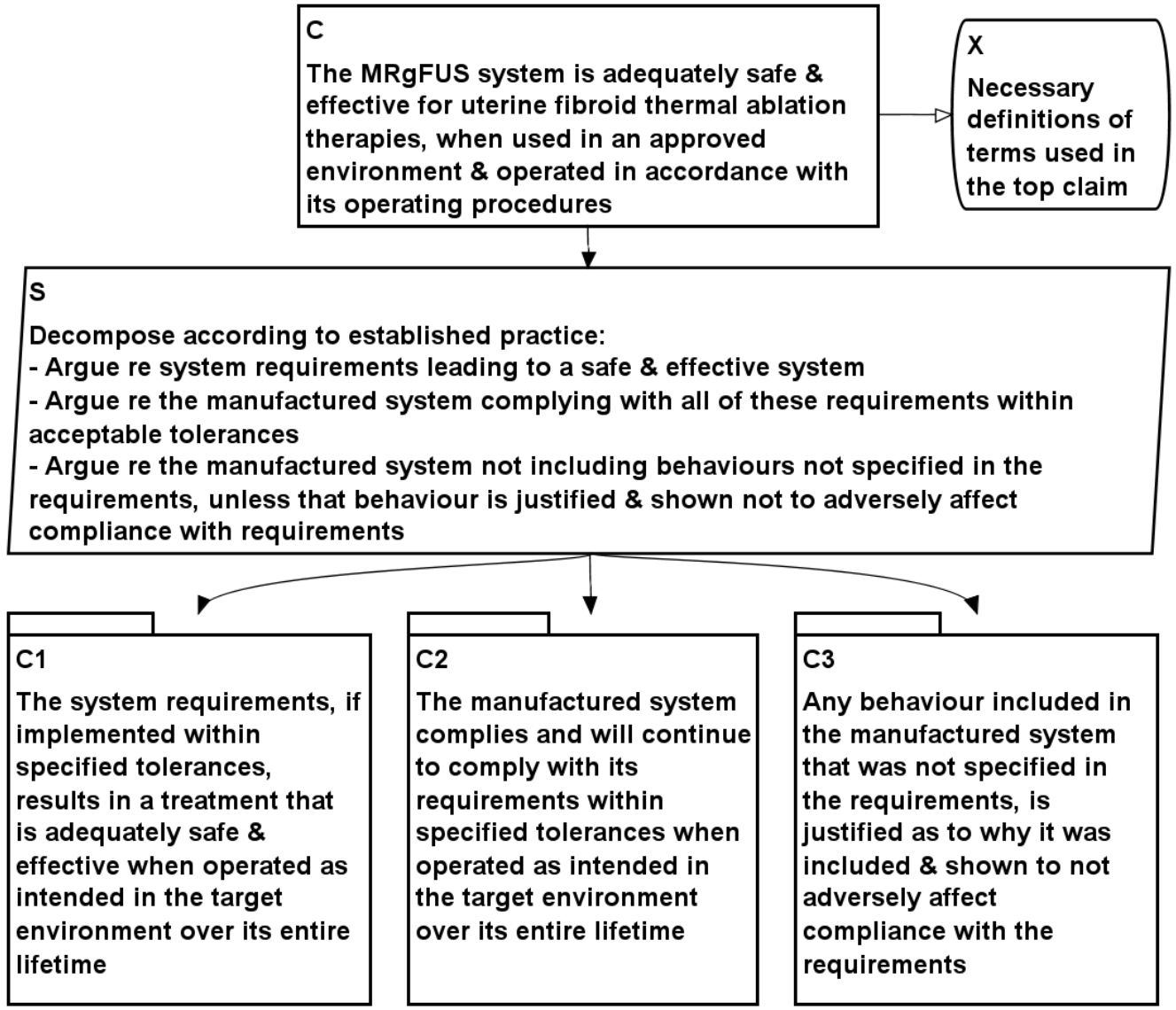
Case Study: MRI Guided Focused Ultrasound

- Can be used for several different treatments
  - Uterine fibroid thermal ablation
  - Enhanced drug delivery
  - Gene delivery
- Different patients undergoing the same treatment for the same pathology can, and often do, react differently



Initial Attempt: Monolithic Assurance Case



What went wrong?

- Monolithic assurance case
  - Becomes unwieldy; Number and complexity of use-cases results in massive assurance cases
  - Difficult to parse and discuss argumentation due to large size and scope, as well as cross-cutting concerns across branches

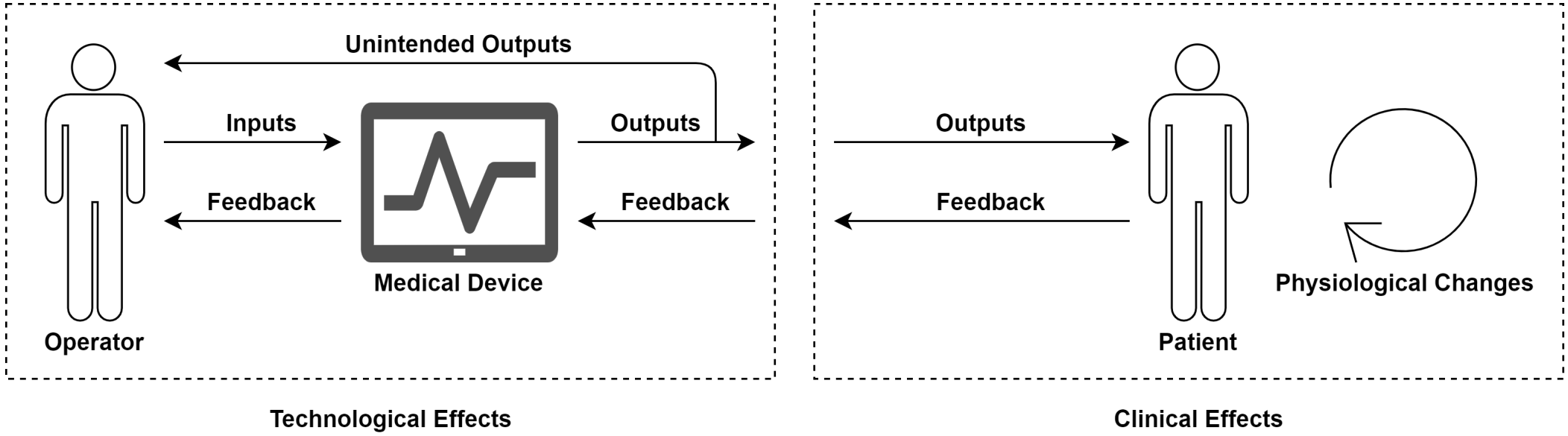
- Treatment Versatility & Patient Variability
  - Needs to contain argumentation on the system's behaviour over several completely different treatments
  - Needs to cover the varied responses different patients can experience when given the same treatment

Rethink Assurance Approach

- The difficulty in assuring such a medical device comes from the clinical side
  - Low behavioural overlap across treatments
  - Variability in responses of patients undergoing the same treatment
  - Treatments may be removed, modified or added throughout the lifespan of the medical device

- What if we could separate the assurance argumentation in a way that preserves safety as a systemic property while helping us manage these difficulties?

Technological & Clinical



Technological Effects

- Consider the medical device solely as a system that produces deterministic outputs given specific inputs

- Technological Effectiveness: How well does the system produce the outputs when given a corresponding set of inputs?
  - i.e. Ultrasound focus positioning, amplitude, duty cycle, timing, etc.

- Technological Safety: How safe is the system when producing the outputs?
  - i.e. Enforced power limits, safeguards against emergent behaviour, etc.

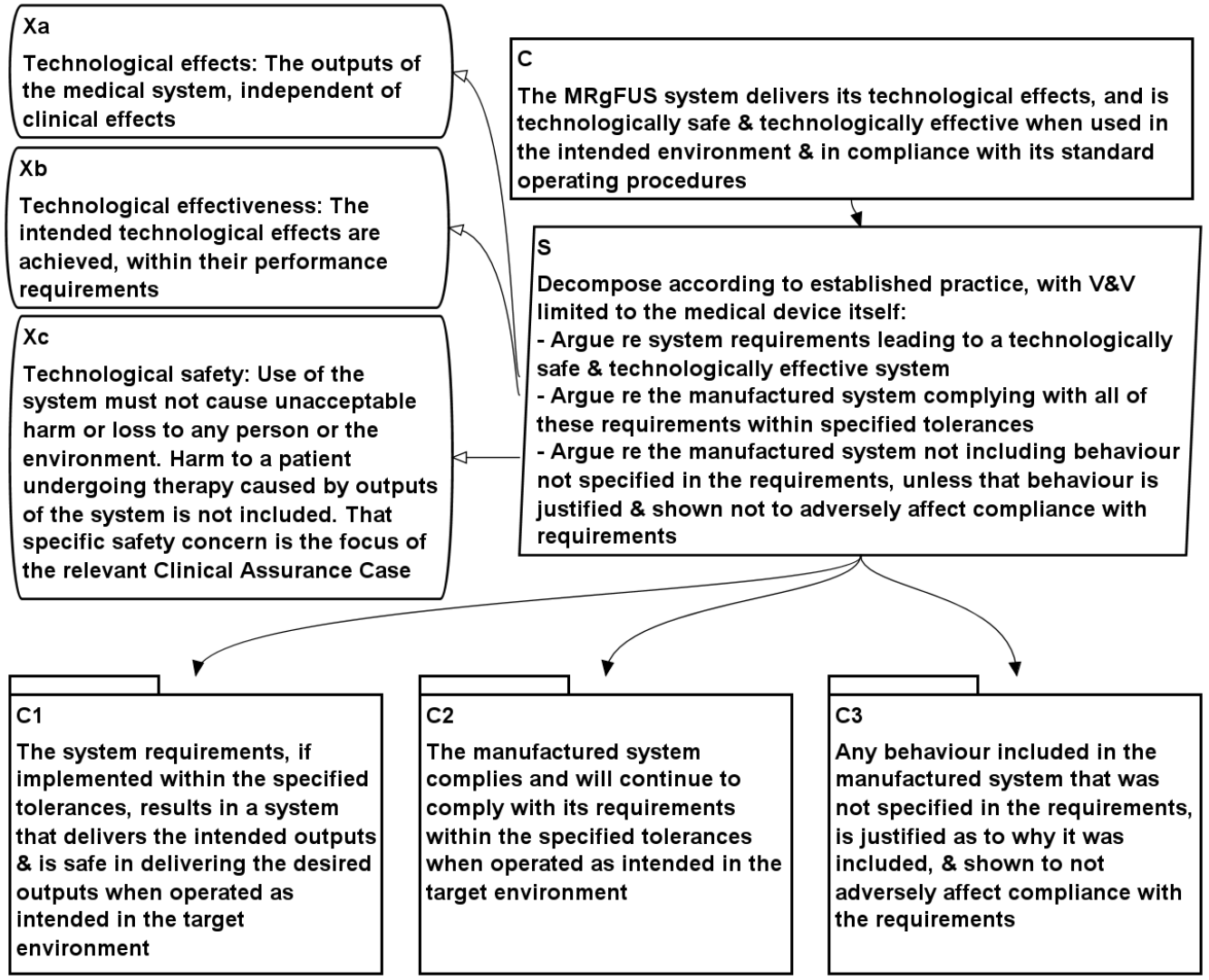
Clinical Effects

- Assuming the technological effects are sound, consider the medical device in relation to how it can be used to provide safe and effective treatments to a variety of different patients

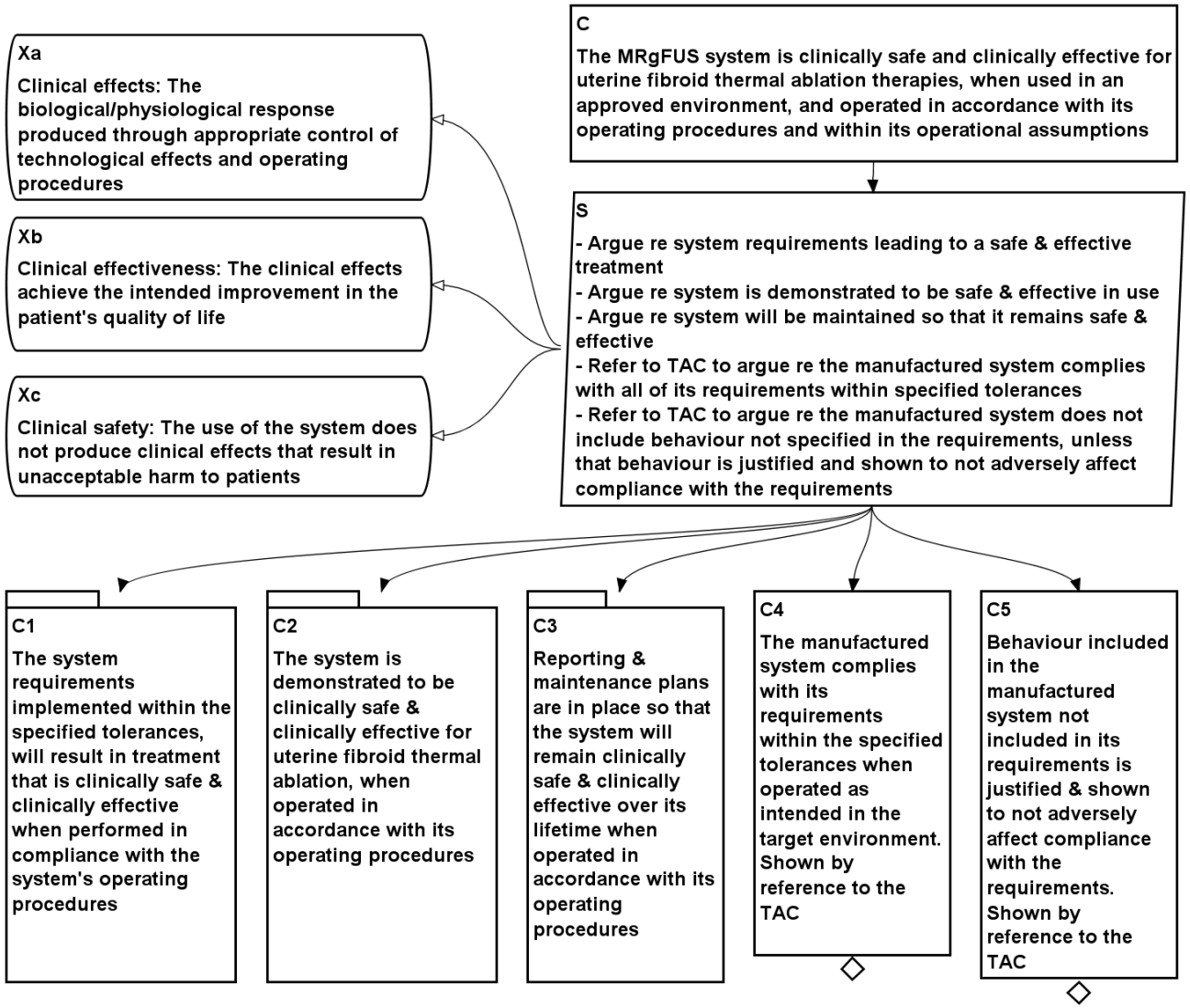
- Clinical Effectiveness: How well does the system produce the intended physiological changes in the patient and/or resolve pathology?
  - i.e. Adequate energy deposition in targeted tissue, acceptable clinical trial outcomes

- Clinical Safety: How safe is the system when producing the outputs?
  - i.e. Energy not deposited in unintended tissue, adverse events within acceptance

Technological Assurance Case (TAC)



Clinical Assurance Case (CAC)



How does this separation work?

- There is only one TAC that focuses on the capabilities of the medical device as a machine that produces a set of outputs when given a corresponding set of inputs
- There are several CACs; one for each treatment type the system will be performing
  - The system isn't just the medical device. The operating procedures, clinical staff, and patients are all part of the system in a clinical context

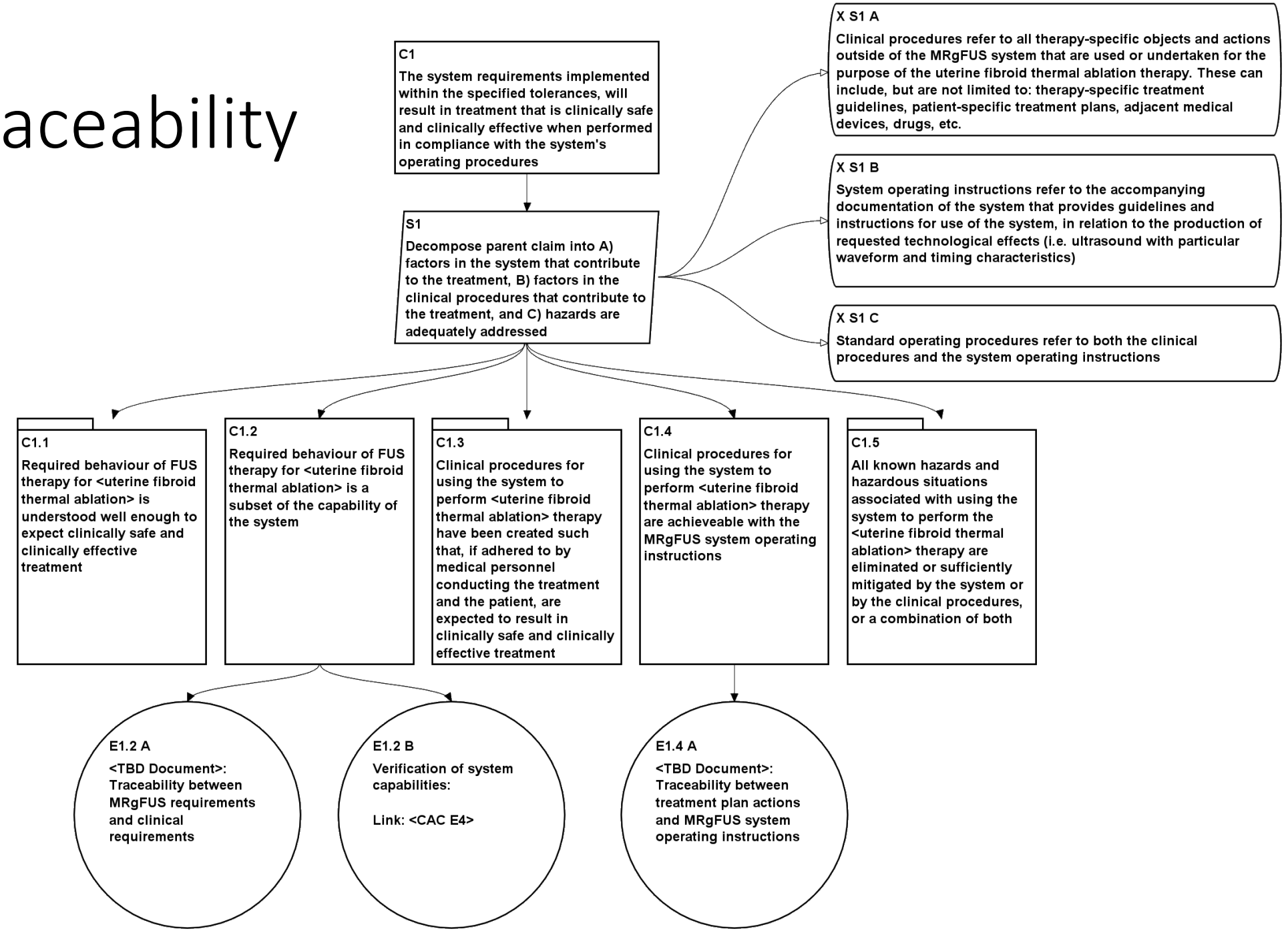
- Ideally, we only need to have one TAC for the medical device, and can update, add or remove CACs as treatment options for the system as it changes over its lifespan

What Evidence Belongs in Each?

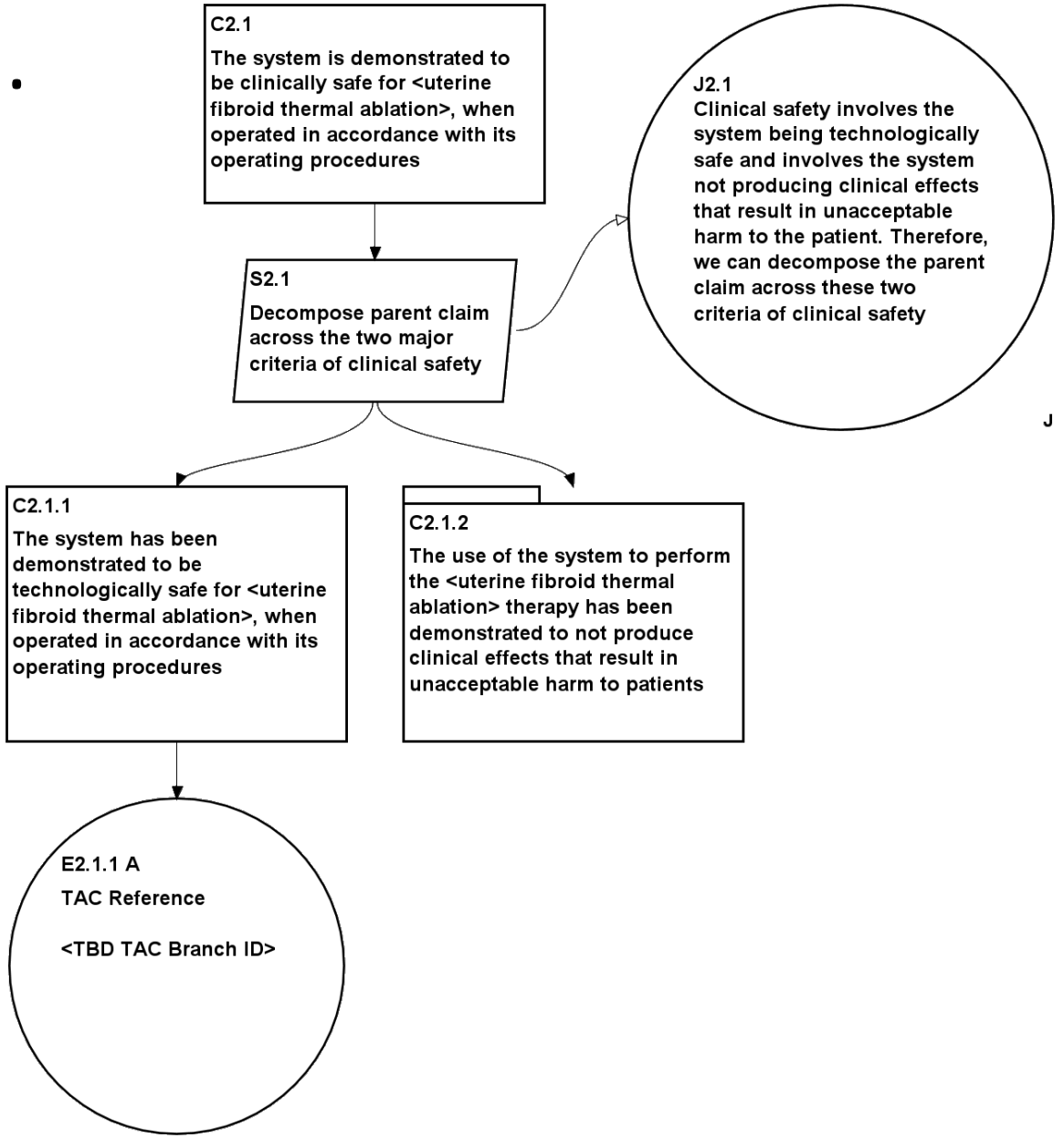
- Evidence in the TAC
  - System hazards mitigated (i.e. standard operating procedures)
  - Energy levels, targeting, and timing of ultrasound waveforms within tolerance

- Evidence in the CAC
  - Thermal ablation of uterine tissue demonstrated
  - Resolution of uterine fibroids; size of fibroids decrease and pain improvement
  - No unacceptable harm; all harm to patients is deemed acceptable according to the risk-benefit analysis of the treatment

Traceability



Traceability Cont.

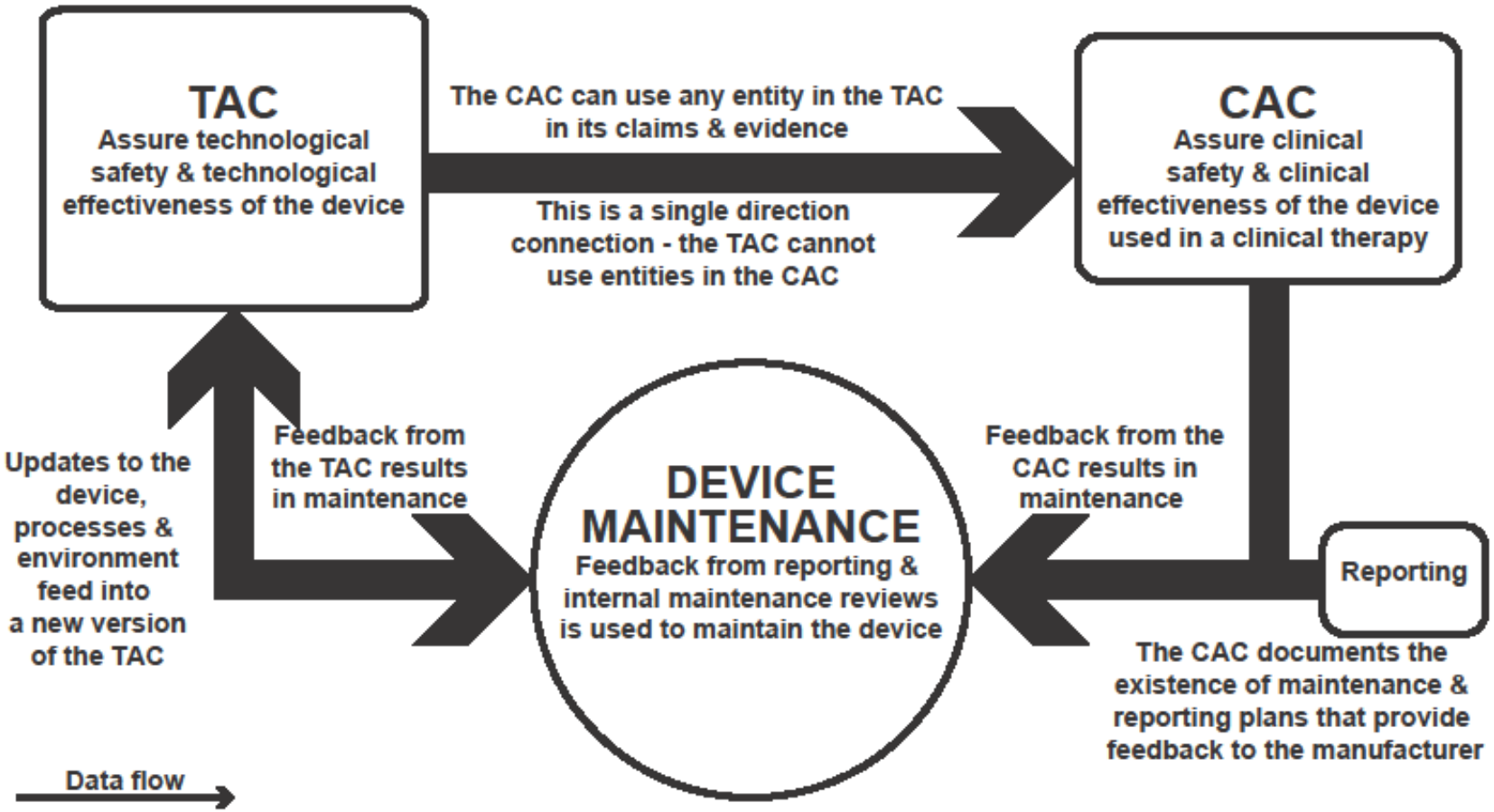


Preservation of Safety as System Property

- Safety is a global system property, so how do we preserve this?

- The CACs argue safety as a global system property, in a similar manner to the argumentation in the monolithic assurance case
  - Contains all of the argumentation for safety and effectiveness, including the material in the TAC, but instead of duplicating its entirety, we only need to reference branches as needed

TAC & CAC over the System Lifecycle



Next Steps

- Develop assurance case templates that can be reused for specific types of medical devices
- Investigate the viability of CAC templates that can be reused across different types of treatments
- Determine applicability of the approach to medical devices with more restricted scope
- Determine if the approach may have use in other industries

Conclusion

- We have introduced a new assurance method for medical devices that preserves safety as a systemic property, while aiding in management of complex multimodal systems

- The separation of concerns with regards to the technological and clinical aspects of a medical device have been useful in constructing strong argumentation in an MRI guided focused ultrasound case study