# STPA DRIVEN DESIGN

## INFORMING DIGITAL TWIN DEVELOPMENT & LESSONS LEARNED FOR FACILITATORS

07 JUNE 2023

MIT STAMP WORKSHOP 2023


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# MEAGHAN O'NEIL, SYSTEMS PRACTITIONER
# 19+ YEARS DESIGN AND DELIVERY EXPERIENCE IN SAFETY CRITICAL SYSTEMS

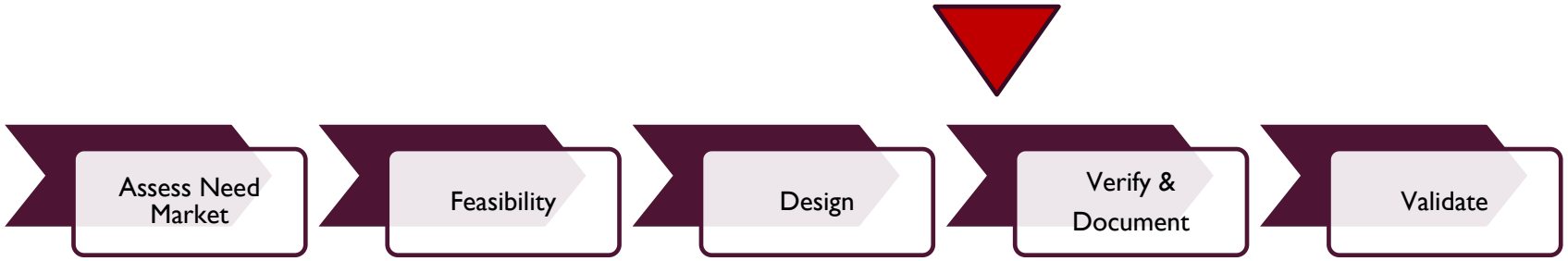
- **System Safety experiences with systems including products and services** Medical Device, Healthcare Services, Power Generation, Fire Fighting PPE and control systems, Infrastructure, Manual and Automated Manufacturing, Visual Inspection, Automotive, Aerospace, Rail
- **Provide extensive systems consulting experience.** Founder of System Design and Strategy Ltd, previous experience at Accenture and Cambridge Consultants. Experience providing systems consulting and training to a wide range of industry sectors worldwide.
- **Contribute internationally to progress the state of the practice of system safety and system engineering practices.** Leader (10+ years) International Council on Systems Engineering (INCOSE), Co-chair International Systems Safety Working Group, Elected International Treasure/Officer INCOSE Board, Co-chaired International Biomedical Working Group.
- **Education and research background.** Chemical Engineering Bachelors (Cornell University), System Design and Management Masters (Massachusetts Institute of Technology), dissertation on System Safety Approaches Applied to Healthcare Adverse Events. Experience in Genetics, Healthcare and Systems Research.
- **General Aviation Pilot:** FAA Commercial Single Engine License, Instrument Rated

# STPA HIGHLIGHTS

- Master thesis, MIT; Dr. Nancy Leveson
  - Application of CAST to Healthcare Adverse Events (2014)
- System responsibilities as director level leader and as consultant:
  - Director for System Engineering and responsible owner for Risk Management, Class I and II medical device which included STPA and other methods
  - STPA trainer, facilitator
  - External reviewer of system safety approaches and safety critical system designs
  - Applied STPA to identify business development opportunities
- Application in a wide range of systems:
  - Medical Device (Class I and Class II), Biomedical Reactor Design, Healthcare Deliver, Power Generation and Storage, Fire Fighting PPE and Control Systems, Infrastructure, Manual and Automated Manufacturing, Visual Inspection, Automotive, Aerospace, Rail

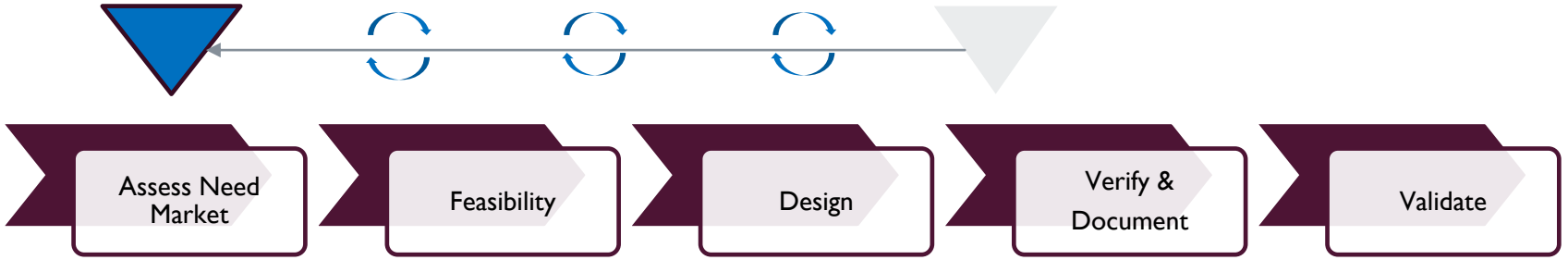
# RECAP ON PREVIOUS FOCUS: COMPARING STPA APPLICATIONS BASED ON WHEN IT IS APPLIED

*STPA Applied After Design*

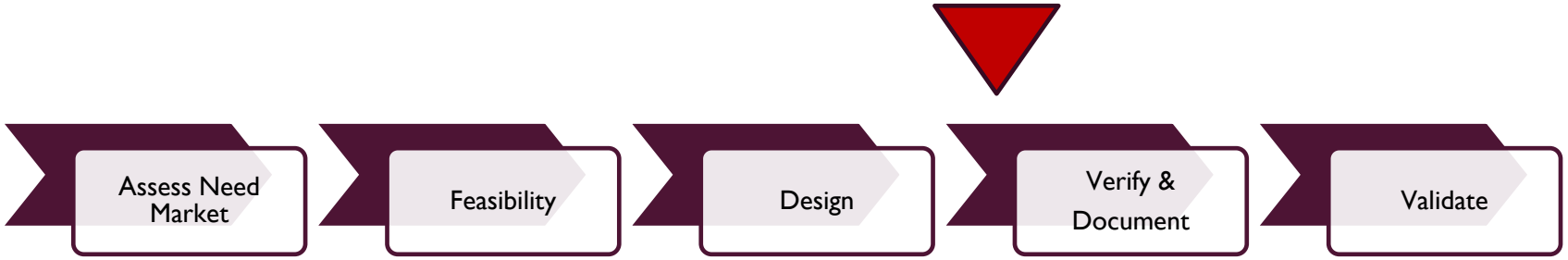



*"Versus"*

*STPA Applied Early and Iteratively*



# FIRST APPLICATIONS OF STPA OFTEN OCCUR LATE IN A PROGRAM SCHEDULE




*Common reasons:*

<u>External consultation:</u>

- Unresolved concern(s) at entry to formal testing
- First time applying STPA internally falters

<u>Internal application:</u>

- STPA applied when design FMEA's sessions are scheduled

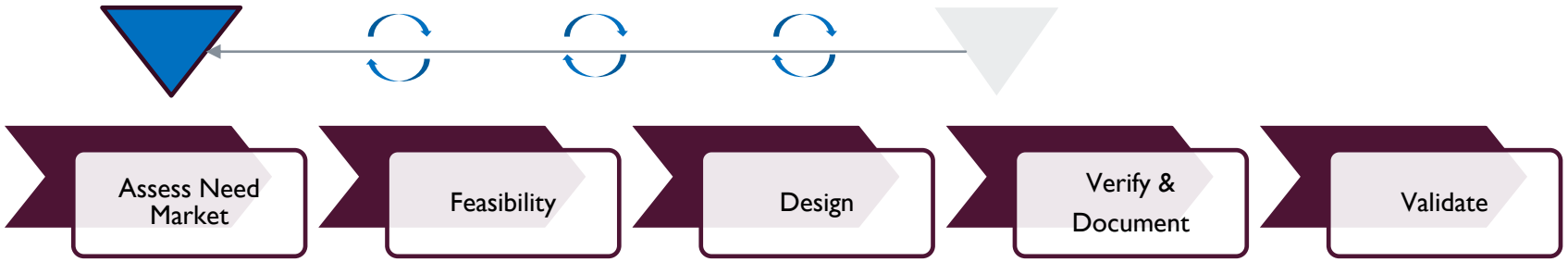
*Common challenges that result*

- Design "freeze" leads to high resistance to change (launch date inertia)
- Viewed as documentation exercise for a regulatory filing, not part of design
- Time with designers may be limited
- "Blame culture" common when late changes realised

| Phase when error is detected and fixed | Cost to Fix |
|---|---|
| Requirements | x1 (reference) |
| Design | x3 - x8 |
| Build | x7 - x16 |
| Test | x21 – x78 |
| Operations | x29 – x1615 |

INCOSE UK Z3 Guide
Primary Reference: "Error Cost Escalation Through the Project Life Cycle", Haskins et al, Proceedings of INCOSE International Symposium 2004.

# APPLY STPA EARLY AND ITERATIVELY THROUGHOUT DESIGN PROCESS TO MAXIMIZE BENEFIT




*Benefits:*

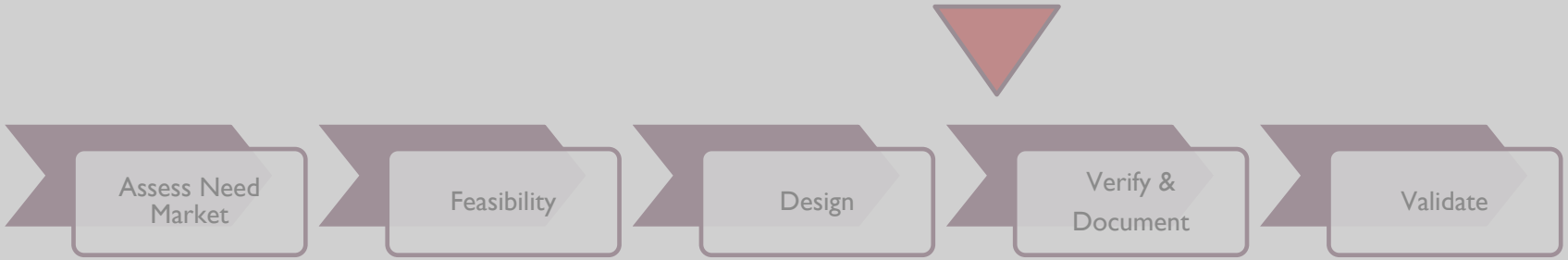
- Can allow a core team to become familiar and practiced with the method
- Hierarchical Control Diagrams can be less challenging to define at system level
- Design tool that enables safety driven design

*Common pitfalls to avoid*

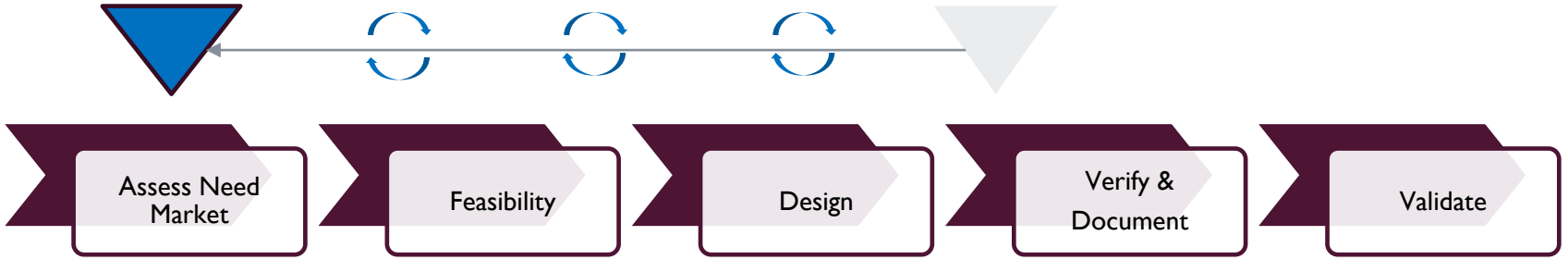
- Viewed as a preliminary hazard analysis and not maintained as design changes
- Schedule does not account for time needed
- Discussions but not documented
- Viewed as time based activity; has been "completed" therefore "sufficient"
- Focus on time / cost savings leads to false expectations as "silver bullet"

# THE FOCUS OF THIS PRESENTATION IS THE APPLICATION OF STPA EARLY IN THE DESIGN PROCESS

*STPA Applied After Design*




*STPA Applied Early and Iteratively*

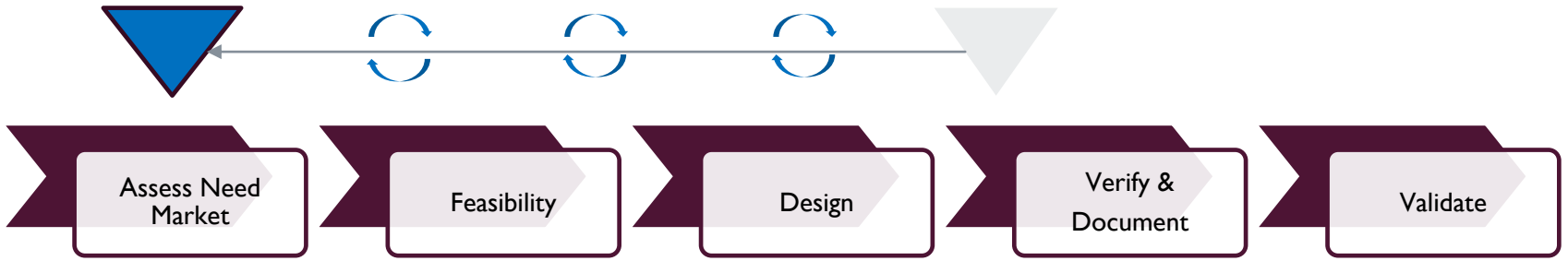


# LESSONS LEARNED FROM A PRACTITIONERS PERSPECTIVE

1. Facilitation → 2. Exploration → 3. Focus

Focus of this presentation is on the application of STPA early in the design process

*STPA Applied Early and Iteratively*



# FACILITATION: RECOMMENDATIONS FOR FACILITATION OF STPA IN PRACTICE IN EARLY-STAGE DESIGN

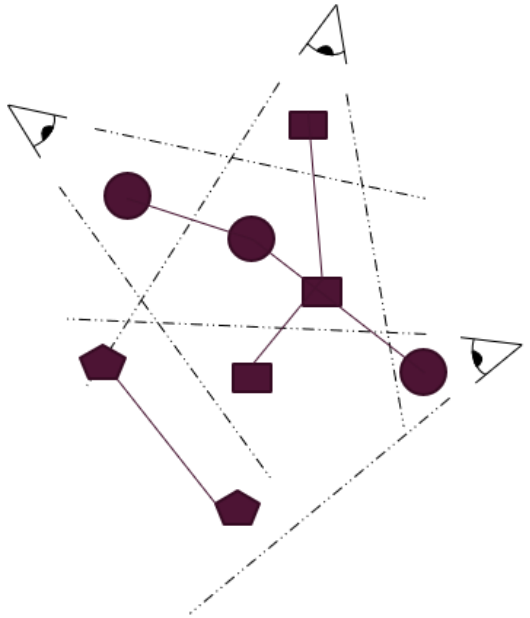
1) Consider Context and Tailor
2) Value Diversity and Plan for It
3) Partnership and the power of 2
4) Commonly Overlooked Opportunities

# 1. CONSIDER THE CONTEXT OF YOUR STPA ANALYSIS AND TAILOR YOUR FACILITATION APPROACH ACCORDINGLY

- Level of STPA experience
- Programmatic Schedule Pressure
- Approach to analysis
- Documentation approach

# 2. VALUE DIVERSITY AND SEEK IT OUT; DON'T FORGET TO CONSIDER HOW TO ADJUST YOUR APPROACH

- System Perspectives
- Group versus interviews
- Objection handling and common areas of confusion



# 3. THE POWER OF 2: PARTNERING IN STPA FACILITATION CAN BE HIGHLY EFFECTIVE

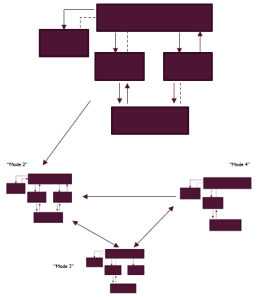
- No position is perfect; there are different advantages to being internal versus external
- Cross disciplinary pairing can be highly effective
- Knowledge pairing: Method, Domain, Enterprise, Culture, Design Process

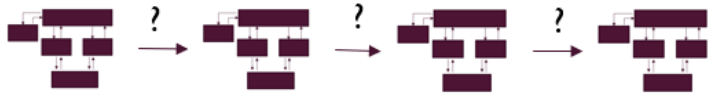
# 4. COMMONLY OVERLOOKED AREAS OF STPA

- STPA Step 1: Assumptions
- Operational Reality
- Current and New
- Dynamics of Control Structure
- Purpose (confusing ends, ways, means)


# EXPLORATION: EVALUATE THE DESIGN SPACE EFFICIENTLY AND EFFECTIVELY

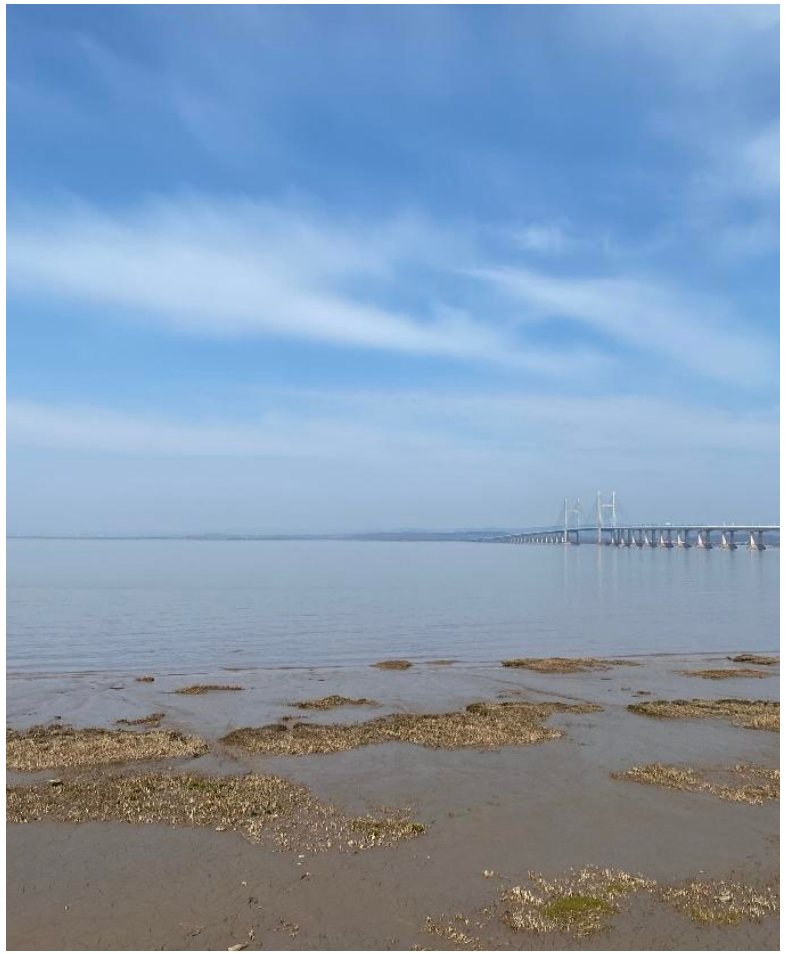
1) Opportunity
2) Approach: Model and Simulation
3) STPA Driven Design for Synthetic Environments, Digital Twin





# FOCUS: GAINING INSIGHT AND AIDING DECISION MAKING

1) Areas of concern, opportunity
2) Communication to stakeholders
3) Managing expectations



# LESSONS LEARNED FROM A PRACTITIONERS PERSPECTIVE ON STPA APPLIED IN EARLY-STAGE DESIGN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