

Deciding How to Decide: Let Your Values Be Your Guide

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ABSTRACT

- Most of our decisions are constrained by “realities” like budgets, time horizons, infrastructure or policies. But what if they weren’t?
- Our quality assurance audit team confronted this problem in the fall of 2018 as we embarked on extensive revisions of our policies and procedures (P&Ps).
- With everything on the table, we immediately turned to “experts,” other groups’ P&Ps, feedback from the people we audit, guidance from regulatory bodies, and documented best practices—and we combed through our own data.
- We discovered that while helpful, there was no “one way” to achieve our goals.

GOALS TO BE ACHIEVED

1. To develop effective P&Ps as well as standard operating procedures (SOPs) which advance the mission of the Cancer Center in general and the Quality Assurance and Safety Monitoring Committee in particular.
2. To have P&Ps and SOPs which reflect best practices and the current regulatory environment.
3. To improve our stakeholders’ experiences with audits and the auditors.

QASM’S VISION

An objective source of support to clinical trial teams; providing an opportunity to evaluate and improve operations to ensure reliability of data and protection of participant rights.

METHODS

1. Establish team values, a team vision, and mission statement.
2. Clarify how our team works within that vision and mission.
3. Allow our values, vision, and mission to constrain decision-making in the development of our P&Ps and SOPs.



QASM’S MISSION

To perform systematic and independent examination of trial-related activities and documentation. This examination will assess whether evaluated activities were appropriately conducted according to the study protocol, standard operating procedures (SOPs), federal regulations and good clinical practices (GCPs) and will confirm that data were generated, recorded, analyzed, and accurately reported.

RESULTS

- We have been able to concentrate on selecting policies and procedures that move our vision forward. By filtering ideas through a matrix of “how does this make us a better partner with teams,” or “how does this make us better advocates for patient safety,” we have made better decisions about critical issues like which studies to audit, case selection, and audit frequency.
- We have developed a cohesive understanding of “who we are” and “what we do”. Because of this we have been able to make better choices outside of our policies and procedures, including how we provide education and how we communicate.
- Our group decision-making has been supported by our values, vision and mission.

CONCLUSIONS

- Crafting these common values, vision and mission was time intensive, but we continue to reap the values of our efforts.
- The tool allows us to envision our future, and face challenges head-on.
- Creates a safe space for a market-place of ideas.

NEXT STEPS

- Continue to work on sharing our vision and mission.
- Continue to evaluate how our vision and mission shape our policies and procedures.
- As we implement new policies and procedures, continue to provide ongoing review of their “fit.”