Proactive Quality Assurance through Dual Review of Eligibility and Consent

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BACKGROUND

Enrolling participants on clinical trials that meet protocol specified eligibility criteria not only establishes a homogenous patient population allowing for adequate data analysis, but it is also critical for the safety and well-being of participants. Factors that might impact consent eligibility deviations include:

- Protocol complexity continues to rise.
- Staff turnover.

METRICS/GOALS

• Reduce the number of deviations related to consent and eligibility compared to the number of participants enrolled on therapeutic trials.

METHODS

Dual Review of Eligibility and Consent confirming the following as shown in Figure 1:

- Eligibility criteria appear to be met.
- Consent forms are complete.
- Informed consent process is documented.
- Screening procedures have been completed with results.
- Regulatory requirements and version control.
- Training, delegation, and 1572, if applicable.
- General GCP/ALCOA+ standards have been followed

OUTCOMES

Overall, we've seen a decrease in the percent of deviations related to consent and eligibility from 7.5% in 2016 to 2.5% of total accruals in 2021 as shown in Figure 2

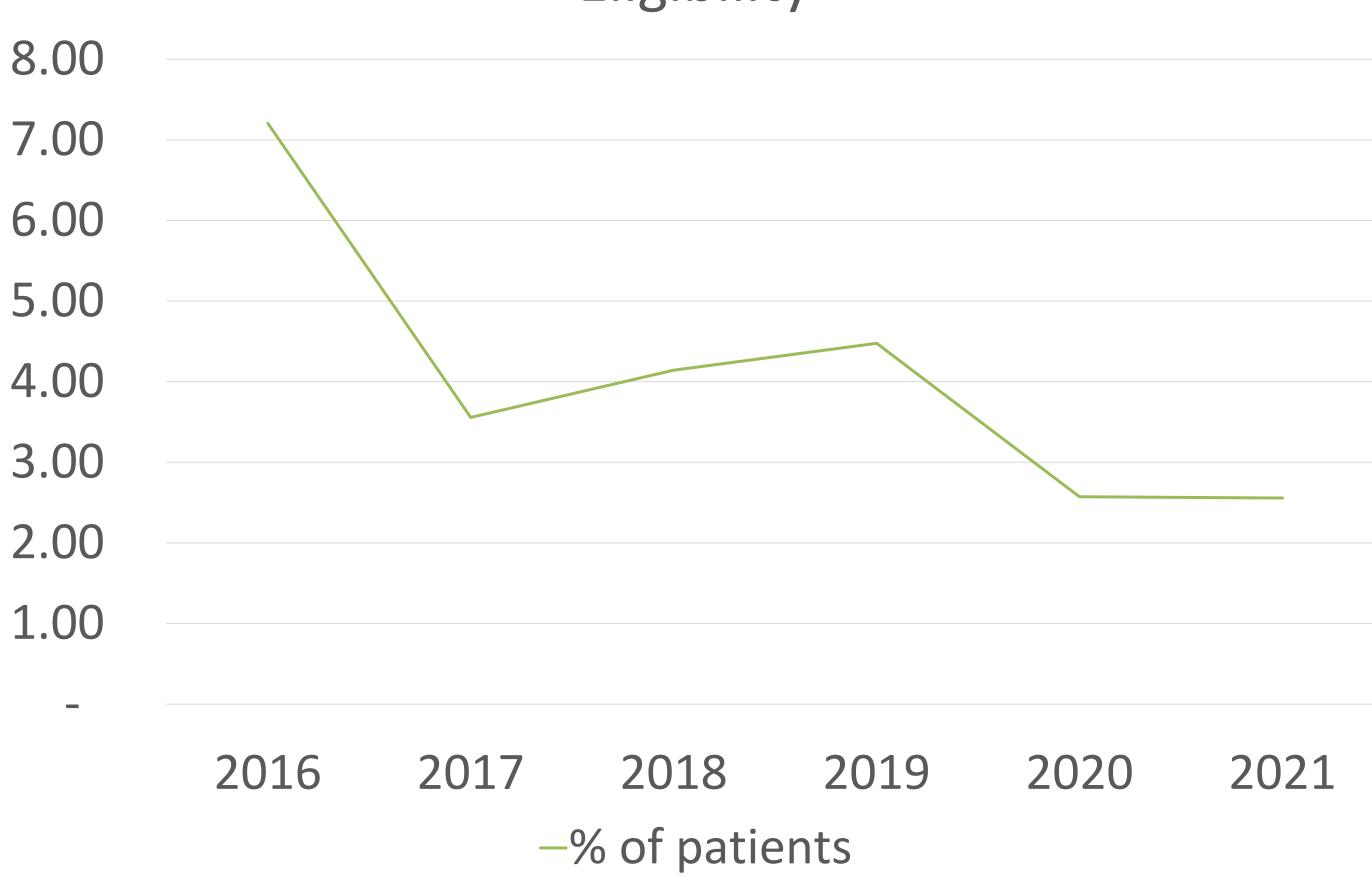
Figure 1

ELIGIBILITY AND CONSENT REVIEW

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% of Newly Enrolled Patients with Deviations related to Informed Consent or Eligibility



LESSONS LEARNED

Since implementing an SOP, HCI has made many adjustments to streamline the process including the following:

- Original SOP allowed another CRC to perform the review and we updated the SOP so that dual review must be performed by a Manager or QA professional.
- We added a review for registration/stratification/ randomization assignments for accuracy prior to enrollment.
- Departmental review of re-consents was added.
- Reviews account for hybrid, virtual setting such as confirming witness, Adobe Sign is Part 11 compliant, etc.



