



# Optimizing Institutional IPEC Report Scores

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## Background

The Institutional Performance Evaluation Committee (IPEC) report is distributed to Alliance institutions twice a year. The IPEC report is in place to ensure Alliance member institutions meet high quality standards in the conduct of clinical research. The IPEC score is compiled from three primary areas: quality, timeliness, and participation in Alliance institutional audits on a volunteer basis.

Quality is measured in several areas including patient ineligibility, institutional Alliance audit results, specimen condition, and early termination of patient follow-up. Data submission, query resolution, and specimen submission comprise the Timeliness score. The Quality and Timeliness scores are the primary focus when the IPEC reports are received.

The IPEC report is an opportunity to educate Clinical Research Professionals (CRPs) on the importance of maintaining a high quality standard on all Alliance trials.

## Aims

The main priority is to not only keep the institution's IPEC score in the satisfactory range, but also to consistently show improvement in both the individual scores and the overall score. This involves monitoring several aspects of each study and building a strong training and education foundation for each CRP.

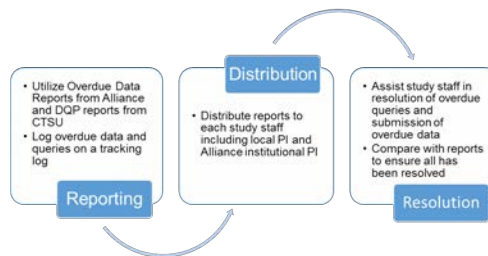
- Institutions who have a substandard IPEC score (< 0) will receive either a warning or can be placed on probation until the score is raised.

## Methods

### Timeliness

The primary focus is the institution's Timeliness score. A meeting is conducted to determine each person's role and to educate the research team on why data and tissue submission and query resolution is essential to the overall conduct of the study.

In order to increase the Timeliness score, this process for monitoring data submission and query resolution was put in place.



- Utilize Overdue Data Reports from Alliance and DQP reports from CTSU
- Log overdue data and queries on a tracking log

- Distribute reports to each study staff including local PI and Alliance-institutional PI

- Assist study staff in resolution of overdue queries and submission of overdue data
- Compare with reports to ensure all has been resolved

### Quality

A large part of the Quality score comes from the institutional Alliance audit. The Alliance and CTSU e-mail blasts are monitored every month for protocol amendments. As soon as an amendment is released for an Alliance study, the research team is alerted to the amendment and the submission timeline (30 days for CIRB, 90 days for non-CIRB). The submissions and IRB approvals and acknowledgements are tracked closely to ensure the study team is abiding by the specified deadlines.

## Results

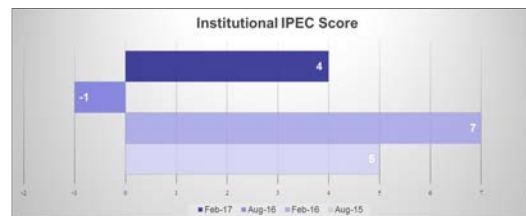
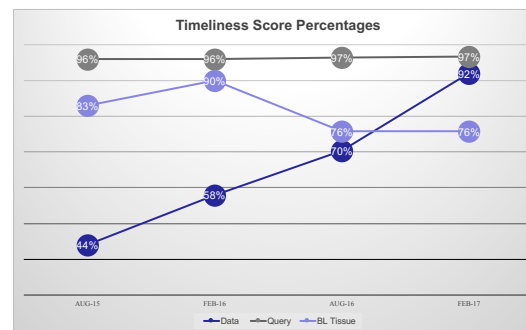
### Timeliness

Prior to implementing the monitoring and education plan, the institutional Data Submission score was -2 with 44% of data submitted on time (8/31/2015 report).

Implementation of the monitoring plan began within one month of receiving this report and took approximately three months before full execution. On the following IPEC report, our Data Submission score remained at -2, however the percentage of data submitted on time was 58% (2/29/2016 report), a 32% increase which was very promising. One year later, our Data Submission score increased to 2 with 92% of data submitted on time (2/28/2017 report), an astounding 109% increase from before the plan was implemented. The Query Resolution score has remained constant at 2 with average of 96% of queries resolved on time.

### Quality

The institution scored Acceptable, Needs Follow-Up on the Alliance audit demonstrating a score of 0 in all three categories (IRB, Pharmacy, and Patient Case Review) which is an automatic 6-point deductions. The audit monitoring plan was implemented after this audit and results of the plan's efficacy will be available after the next audit in 2019.



## Conclusion

The monitoring and education plan implemented in this institution has not only increased the institutional IPEC score, it has also increased CRP awareness of the importance of data quality, timely data and tissue submission, and adherence to regulatory deadlines. It is very important that the institution has something in place to ensure we maintain a high quality standard now and in the future as the reporting structure evolves.

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