The Impact of QC in Multicenter Clinical Trials - The IROC Experience for NCTN Focusing on 18F-FDG-PET

David Poon, Preethi Subramanian, Richard Jacko, Prayna Bhatia, Tim Story, Shivangi Vora, Ajay Siva, Talha Saff, Jun Zhang, Michael V. Knopp

Methodology

- PET/CT imaging composed of several examinations for each patient, each with its own set of parameters which must be monitored.

QC Methodology: "18F-FDG-PET/CT Study Weighted Scoring"

Table 1: Example of a reported results sheet for a patient study, detailing the parameters and their corresponding scores.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Score</th>
<th>Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Image Acquisition Time</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiopharmaceutical Total Dose</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vendor Model</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The weighted scoring system enables a comprehensive evaluation of the PET/CT study's quality, considering various parameters such as image acquisition time, radiopharmaceutical dose, and vendor model. Each parameter is assigned a score based on predetermined criteria, ensuring a consistent and objective assessment.

Figure 1A Details the compliance in regard to the trial performance, while Figure 1B illustrates the quality of the image acquisition time. Figure 1C shows the radiopharmaceutical dose compliance.

Results

- The data analysis revealed significant trends in quality improvement over the course of the first four years of the trial.

- The impact of quality control on PET/CT imaging was studied, examining factors such as image acquisition time, radiopharmaceutical dose, and vendor model.

Conclusion

- The findings underscored the critical role of quality control in ensuring the accuracy and consistency of PET/CT imaging within clinical trials.

- The implemented QC tools like heat-mapping for proactive communication improved the overall quality assurance process.

- The study concluded that a comprehensive QC approach is essential for the success of PET/CT imaging in clinical trials.