An Issue Tracking System to Facilitate the Enhancement of Clinical Data Quality in the Clinical Breast Care Project

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Summary
An online issue tracking (QAIT) system was developed to support the QA of questionnaire-based clinical data and tissue banking in the Clinical Breast Care Project (CBCP). The web-based system provides a centralized storage and management of QA issues and role-based access to related information and functions via internet. The QAIT system greatly improved the QA process for the CBCP clinical data and tissue banking and can be easily adapted to other applications.

Background
The Clinical Breast Care Project (CBCP) is a program that involves multiple clinical and research sites. The storage and management of CBCP data are centralized at one research center. Quality assurance (QA) is conducted at all sites to ensure the highest quality of clinical data and the process is characterized by the participation of people from different sites (researchers, data entry/manager, physicians, nurses, and patients) and by intensive communications. The process involves many steps and considerable time (days to months), before an identified data error can be corrected. The requirements of this process are usually beyond the capability of any available data tracking system. There was, therefore, a need to develop a system to facilitate the communications among multiple sites and to keep track of the QA issues.

Method
An online QA issue tracking (QAIT) system was developed to support the QA of questionnaire-based clinical data and tissue banking in the CBCP. This web-based application is written in PHP and supported by a relational database. The system provides users with role-based access to information and functions for system management, creation and management of QA issues, search, report and export of QA issue data via user-friendly interfaces.

Results
The QAIT system has greatly improved the QA process for the CBCP clinical data and tissue banking by eliminating the bookkeeping efforts and email/phone communications among individual QA team members, and reducing the time to resolve a QA issue. It has enabled our QA team to clear a six month backlog of QA issues within a few weeks. The system currently hosts over 3000 QA issues from >1000 questionnaires or tissue samples. With this system, all of the information needed to resolve QA issues is readily available.

Conclusions
This system is of great value for QA of the CBCP clinical data. It is also easily adapted to other applications where there are QA needs for clinical data and tissue banking.