Neuroendocrine Tumor Collaborative Registry

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Background. Neuroendocrine tumors (NET) are a diverse and rare group of diseases that can be: (i) benign or highly malignant; (ii) asymptomatic or cause debilitating syndromes; (iii) indolent or require highly aggressive therapies; and (iii) originated almost anywhere in the body. To increase understanding of NET, it is necessary to create a standardized, user-friendly, HIPAA-compliant registry that will allow researchers from multiple centers to collect, mine, and share NET-related data.

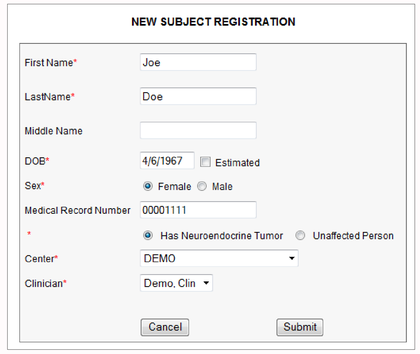
Methods. The Neuroendocrine Tumor Registry (NETR, http://netr.unmc.edu) utilizes a multi-tier web-based architecture and a secure web server communication. All Protected Health Information is stored encrypted in an Oracle 11g Database. The system employs a principle of the federated model: all centers input data in the central repository using the same questionnaire and procedures, while each center manages and has access only to its own data. This model protects the confidentiality of each center's data, while laying a foundation for collaborative research. If desired, each center has the capability to share all or selected portions of data.

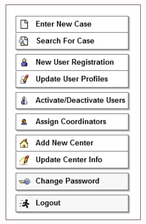
Results. The NETR has been created and tested. Its questionnaire includes patient socio-demographic, lifestyle, environmental, family history, and clinical forms that are designed with predetermined selection choices to assist users with accuracy and ease of completion. The validation components of the NETR prevent users from entering erroneous information. The NETR's end-users are patients, clinicians, researchers and center administrators that have corresponding levels of authority to enter and use data.

Users and Their Authority

There are five user roles, each of which has a particular type of authority:

- *Subject/Patient:* Can enter personal, demographic, lifestyle, medical and family history data;
- *Clinician:* All of the above + Enter clinical data, retrieve and edit existing cases of his/her patients;
- *Coordinator:* All of the above but only for the cases of the assigned clinicians;
- *Center Manager:* All of the above + Retrieve and edit cases of all patients in the center/institution, manage user accounts within the center;
- *System Coordinator:* All of the above + Retrieve and edit all cases, register new centers, manage all user accounts and privileges.





Benefits to Users

- Standardized data elements, vocabulary, and forms for data collection
- Collecting data by effective, secure, and easy to use Web-based system
- Computerized audit and control of data quality
- Ability to collaborate with other centers and to have access to the larger data set (separate agreement with collaborating centers is required)

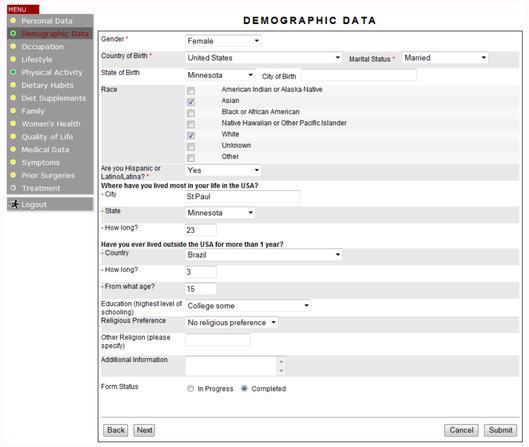
Quality Control

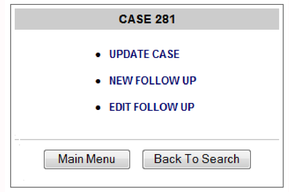
Quality of the collected data is ensured by:

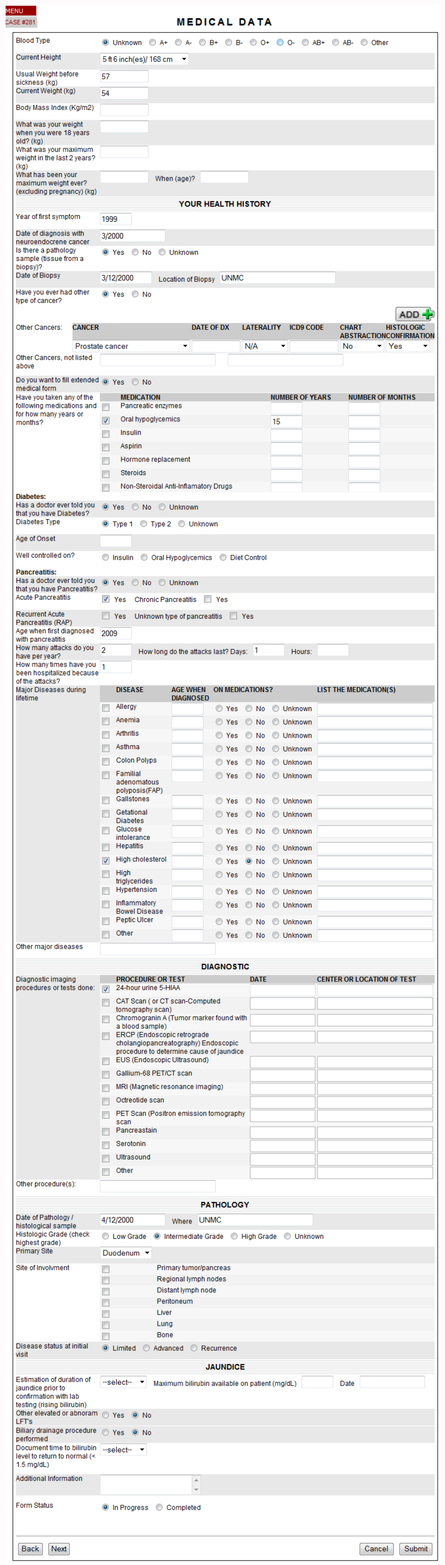
- The standardization of collection forms that have been designed to use predetermined selection choices whenever possible, which improves accuracy and ease of completion;
- Extensive use of automated validation procedures that verify the accuracy of the submitted data;
- Multi-layer control (by clinician, center manager, system administrator) of the quality, completeness, timeliness, and content of the registry data;
- Training and technical assistance to participating centers regarding the operations of the registry;
- Establishing and monitoring compliance with program standards for data completeness and quality.

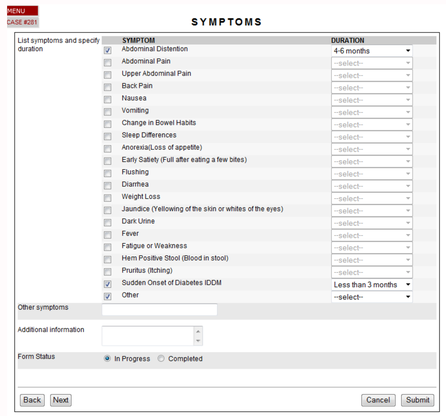
Integration with the caTissue Suite

- The caTissue Suite has been adopted and will be integrated into the framework to manage biospecimen data. Adoption of the caTissue ensures that the biospecimen data are collected in a standard and efficient way and will simplify data sharing.
- The registry's case number will be used to link the biospecimen data with data collected in a registry.









Conclusion

The NETR is ready for implementation. Future developments should include:

- Recruitment of new participating centers and subjects;
- creation of a Steering Committee (consisted of representatives from participating centers and a patient advocate) to govern the NETR;
- Refinement of the NETR's questionnaire by incorporating suggestions from the clinical and research community;
- Coupling the NETR with a biospecimen management system.