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Implementation Of A Data Feedback Loop For Accurate Clinical Annotation Of A Biorepository

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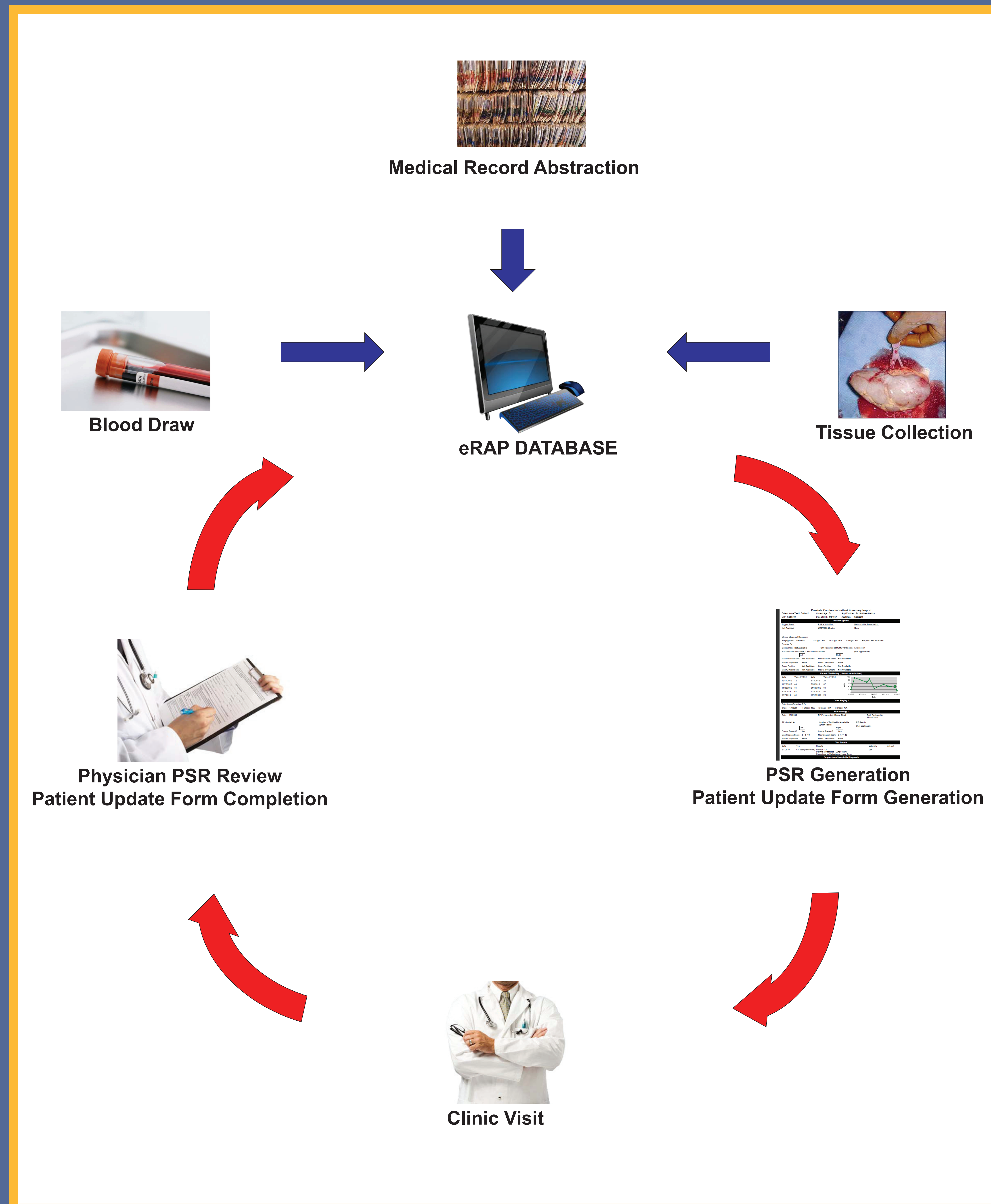
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Background

- A variety of tumor tissue and body fluid repositories have been established to bank human tumor tissue and blood collected from cancer patients.
- The NCI promulgated a Best Practices document emphasizing the need for high quality, clinically annotated human specimens that are linked to donors' clinical information.
- The Mount Sinai School of Medicine Tisch Cancer Institute recently established the Genitourinary (GU) Cancer Biorepository to develop a repository for biomarker development through collection of liquid and tissue specimens from cancer patients at multiple times points during their cancer therapy.
- All specimens are linked to a comprehensive clinical database.
- This GU Biorepository requires ongoing multidisciplinary collaborations to ensure the acquisition of timely, accurate clinical information.

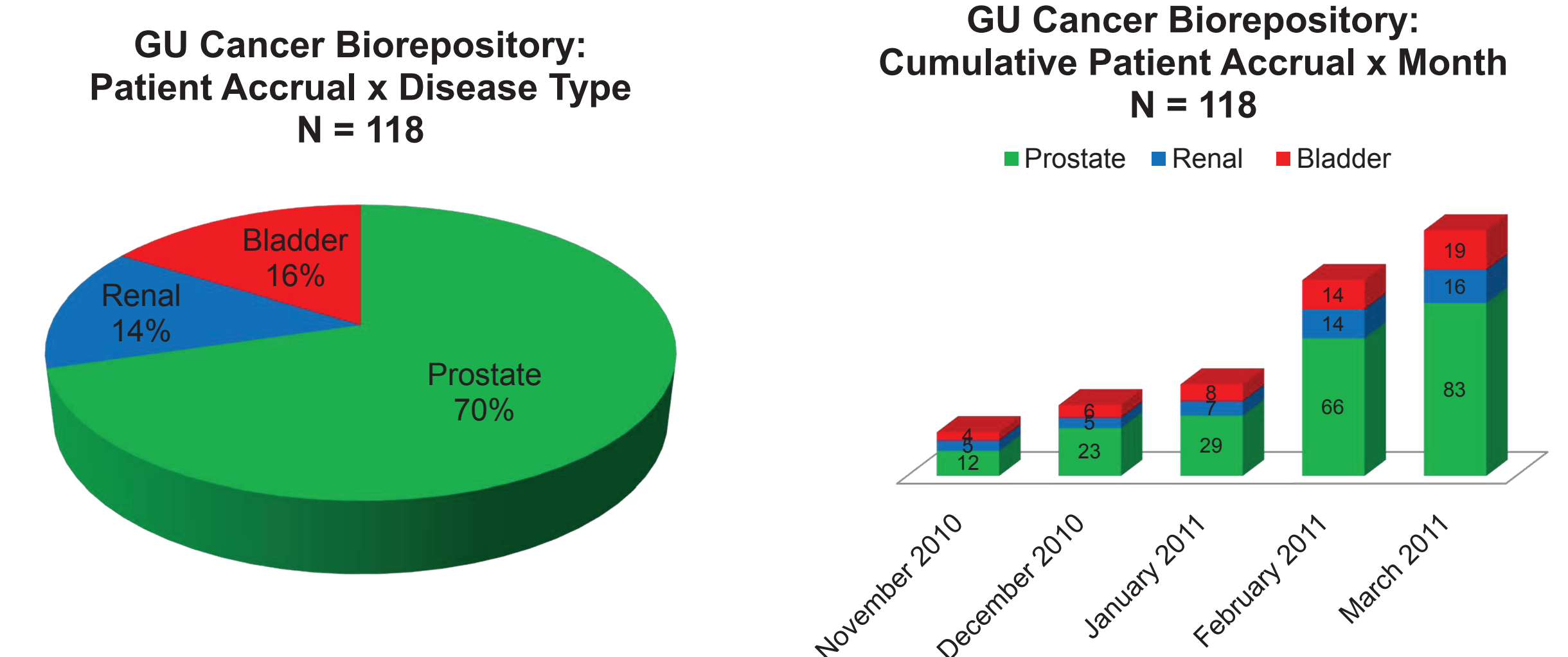
Methods

- All patients with a GU cancer diagnosis irrespective of tissue specimen availability are approached for participation.
- Patient medical records are reviewed and data points relevant to cancer diagnosis, disease progression, and treatment information are entered into a clinical database, the Electronic Research Application Portal (eRAP). Each patient record is coded with a 5-digit Patient ID.
- A blood draw is performed at each standard-of-care (SOC) clinic visit and resulting liquid specimens banked.
- If a patient is scheduled for an SOC surgical procedure, research samples are isolated from any excised tissue and placed in formalin and frozen via Optimal Cutting Temperature (OCT).
- Specimens are entered into an independent Specimen Tracking Database which also requires a username/password combination. Each specimen is coded with a 5-digit Specimen ID. A data link is made between each Patient ID and all associated Specimen IDs.



Results

- **Clinical Data Feedback Loop:** provides current and accurate clinical data to the treating physician and the eRAP database:
 - An automated Patient Summary Report (PSR) is generated which contains real-time detailed clinical information drawn from data previously entered into eRAP from the medical record.
 - Treating physician reviews and updates the PSR and Patient Update Form with information from a new SOC clinic visit.
 - This updated information is entered into eRAP. An updated PSR can then be generated for the next SOC clinic visit.



Conclusions

- The GU Cancer Biorepository allows for the collection of high-quality clinically annotated human specimens by linking each specimen to longitudinal clinical histories that are detailed, thorough, and up-to-date.
- The Clinical Data Feedback Loop provides physicians with an annotated graphical summary of patient data at each visit and includes real time data capture and corrections resulting in reliable high-quality clinical dataset for the research database and by extension, any collected specimens.
- The Mount Sinai GU Biorepository structure and operations is a model for banking well-annotated clinical specimens.

References

1. Office of Biorepositories and Biospecimen Research. *NCI Best Practices for Biospecimen Resources* (2010).
2. Oh WK, Hayes J, Evan C, et al. Development of an Integrated Prostate Cancer Research Information System. *Clinical Genitourinary Cancer* 2006; 5:61-66.