



# Managing Identify Domains for Clinical and Translational Research using WS/PIDS

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## ABSTRACT

A Research Master Participant Index (RMPI) is analogous to an enterprise master patient index (EMPI) in that it links multiple identifiers across an enterprise; however an RMPI must also deal with the complex issues of isolating participant populations in clinical trials and maintaining proper anonymization. The Person Identification Service (PIDS) standard addresses the capability to handle identities in a consistent way and coordinate and correlate identifiers between independent domains. Through Project Sentinel Georgetown University has developed a Web Services-based PIDS (WS/PIDS) that is uniquely suited to solving the RMPI problem. WS/PIDS-based RMPI provides a domain specification that is database independent and also supports a flexible multi-step correlation design that supports correlation, merging/unmerging and linking/unlinking of anonymized as well as non-anonymized IDs, commonly encountered in research imaging environments.

A WS/PIDS-based RMPI has been created to support the unique research imaging environment provided by the Center for Clinical Imaging Research (CCIR) at Washington University in St. Louis. The CCIR merges state-of-the-art imaging technologies and a comprehensive IT infrastructure designed to manage clinical and translational research programs and trials in isolation from the normal clinical routine.

## PROJECT SENTINEL

Project Sentinel is funded by National Library of Medicine under contract N01-LM-3-3506.

Project Sentinel Collaboratory aims to serve as an ever-present watchful guardian of patient health and public safety.

WS/PIDS was developed as an integral part of Project Sentinel. Project Sentinel exposes original PIDS functionality to not just the Web environments but also the Grid environments with "Minimal Dual Use functionality" for use in both routine public health functions and in emergency situations.

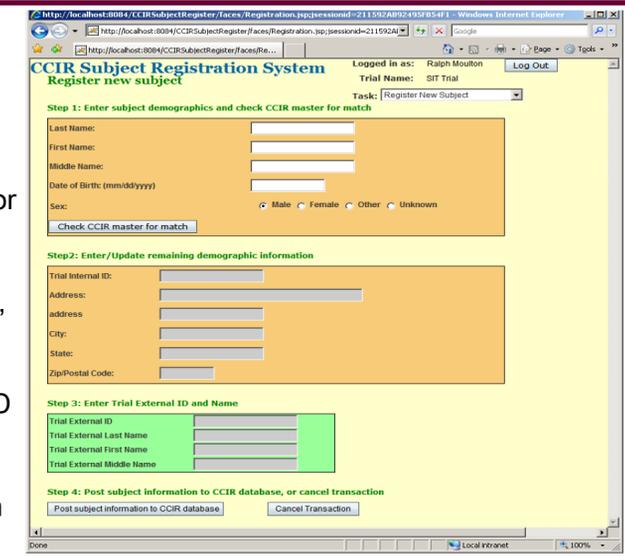
## RMPI SYSTEM DESIGN CONCEPT



## PARTICIPANT REGISTRATION

WS/PIDS is integral to the CCIR Participant registration process.

- When a new trial is instantiated in the CCIR, WS/PIDS automatically creates and maintains internal and external (anonymized) ID Domains for the trial.
- When a new participant is registered for a trial, basic demographic information (e.g., name, DOB, SSN, Sex) is used by WS/PIDS to perform a profile lookup on the RMPI, allowing the user to match the participant to their pre-existing RMPI ID and records.
- WS/PIDS maintains "links" between ID Domain pairs, allowing software to retrieve IDs for a given participant in any Domain.



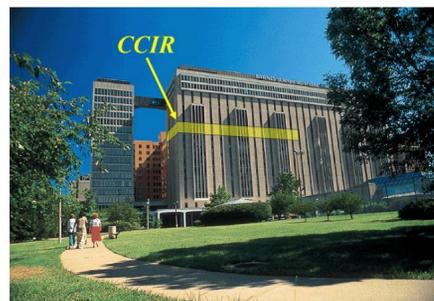
## CLINICAL ID MANAGER

WS/PIDS also manages the relationship between IDs in the RMPI and those in the Clinical domain, even though the actual clinical ID domain is outside of WS/PIDS.

In cases where access to participant clinical data is needed for a trial, and consent for such access has been given, WS/PIDS profile data for the participant is used to format a XML based query, returning candidate IDs from the clinical domain. If a match is found, the clinical ID is added to a "mirror" clinical ID domain in WS/PIDS, and linked to the corresponding RMPI ID, making clinical data queries for the participant possible. If consent is withdrawn, the link and the entry in the WS/PIDS clinical ID domain are deleted, removing access to participant data.

Periodically (e.g. before a query is run) the ID's in the WS/PIDS clinical domain are validated against the actual clinical domain to allow for merges, resolution of temporary IDs and other events which cause changes in the clinical ID domain.

## CCIR Center for Clinical Imaging Research



Advancements in healthcare can be achieved by expanding the use of new bio-imaging technologies both in the clinic and throughout the stages of drug discovery and development. Unfortunately clinical and translational investigators are frequently unable to make use of

imaging because of limited access or unfamiliarity with the latest equipment. Information management and workflow issues, different from clinical practice, must be resolved to achieve the goal of rapid translation of basic science into clinical utility.

To address these issues Washington University School of Medicine has created the Center for Clinical Imaging Research (CCIR). Located in an 8900 square foot space on the 10th floor of the Barnes-Jewish Hospital, CCIR places state-of-the-art imaging technologies dedicated for research use within a hospital environment. A support staff and a unique information technology environment provide researchers with the tools and support they need.

## WEB SERVICE BASED PERSON IDENTIFICATION SERVICE

WS/PIDS, a Web Service defined specification, preserves the intent and semantics of the original CORBA defined PIDS specification and offers extensive multimedia support.

WS/PIDS supports the following interfaces, the semantics of which are defined by the PIDS specification:

- **Identify Person**: uses search values to find the IDs and profiles of closely matching persons;
- **Profile Access**: uses IDs to read or write profile information;
- **Correlation Manager**: matches and correlates identifiers across multiple sources for federation;
- **Sequential Access**: manipulates groups of identifiers;
- **ID Manager**: handles identifiers within one or multiple domains;
- **Identity Access**: treats each person's identity as a distinct information resource.

WS/PIDS also supports an additional interface, which is not defined by the PIDS specification:

- **Domain Maintenance**: creates and maintains domains, manages domain access and allows for persistent storage of correlated IDs.

WS/PIDS is WS-I compliant, platform independent, language independent and interoperable. It supports the main actors of the Patient Identifier Cross Referencing (PIX) IHE profile.

## CONCLUSIONS

- An imaging center dedicated to clinical and translational research has workflow & information management requirements that differ substantially from the clinical norm.
- WS/PIDS provides an elegant, systematic way of establishing and maintaining ID domains, IDs in those domains, and the relationships between those IDs.
- WS/PIDS provides a robust, error-tolerant, profile based lookup which enables users to quickly and accurately identify participants in other domains matching a known participant, and to record that relationship for future use.
- Structured as a web service, WS/PIDS is positioned to provide needed ID domain functionality to any software module requiring it quickly and efficiently.

## REFERENCES

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