Anonymity & Pseudonymity in eResearch via smartcards and Public Key Infrastructure

Stephen Wilson

Managing Director, Lockstep Technologies Pty Ltd
swilson@lockstep.com.au mob: +61 (0)414 488 851

The fastest way to get somewhere is to be there already

Paramahansa Yogananda

The best way to de-identify is to never identify in the first place

Introduction

Much healthcare and social science research requires that study subjects remain anonymous or pseudonymous.

Tensions arise between privacy, authenticity and integrity.

Without compromising confidentiality, reported data must correspond to real subjects, and must resist corruption.

eResearch is conducted in an increasingly stringent regulatory environment, with legislated privacy requirements, and raised confidentiality expectations.

"Stepwise" is a Privacy Enhancing Technology (PET) that de-identifies subjects and assures integrity of their IDs.

Stepwise secretes IDs within anonymous digital certificates and smartcards (or like devices) issued to each subject.

The solution leverages public key infrastructure (PKI) services that are increasingly widespread in the tertiary sector, and can be deployed using a wide range of authentication form factors.

Worked example: Clinical trial confidentiality

Smartcards (or alternatively, USB keys) carry Stepwise IDs and are used at follow up visits to secure data records.

- **Study set-up** (Fig 1): Equip investigators with protocol, subject information packs, data collection software, treatments, and investigator smartcard and reader.
- **Subject enrolment** (Fig 1): explain study, provide information pack, obtain consent, personalise smartcard online, load Stepwise ID (automatically), issue card
- **Follow-up** (Fig 2): Data collated; all personally identifiable information stripped from the record; record digitally signed twice, by investigator's card and subject's Stepwise ID card.

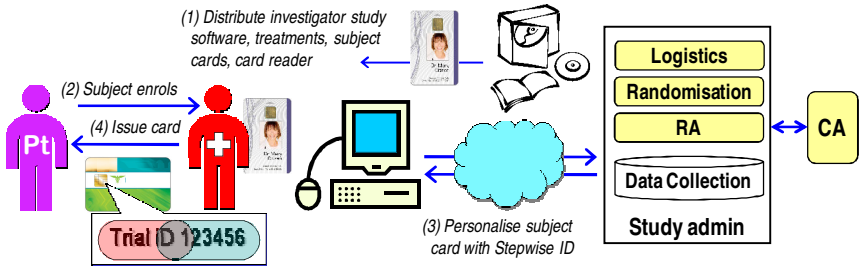

Figure 1: Issuing study subjects with *Stepwise* IDs

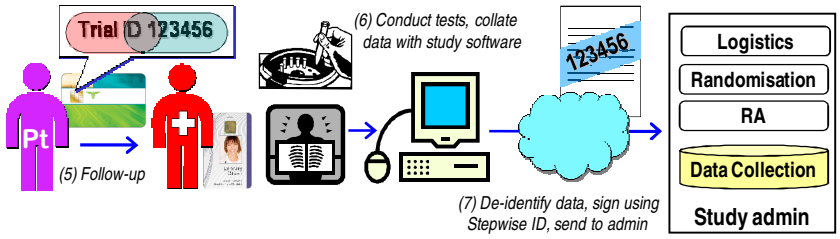

Figure 2: Using *Stepwise* IDs at follow-up visits

Theory

Orthodox PKI entails identity checks and the issuing of general purpose digital "passports". Yet the same digital certificate technology can be used to securely notarise attribute of the user.

Stepwise uses digital certificates to bind a subject's study ID to a private key contained in a chip, such as a smartcard or USB key.

The subject's ID is subsequently bound to data records by way of a digital signature. When the data record is received and the digital signature verified, the receiver is assured that the ID is legitimate and that it has been used with consent.

By enhancing the "pedigree" of personal IDs, *Stepwise* allows all extraneous identification to be dispensed with, dramatically improving confidentiality and privacy.

Benefits

- Fundamentally enhanced confidentiality
- better confidence on the part of subjects
- better privacy compliance
- better study data integrity
- fewer errors
- better resistance to fraud.

Technical Notes – PKI

- The *Stepwise* digital certificate is generated by a conventional Certification Authority (CA) server, available as a managed service in the emerging tertiary sector PKI.
- The certificate request is generated by a registration (RA) module integrated in the study administration system, and signed by the investigator smartcard.
- The private key in the Subject smartcard is accessed via standard protocols (CAPI, PCSC, $XML_{signatures}$, PKCS# and X.509).

Other *Stepwise* applications

- Apomediation
- anonymous online social networking, online counseling
- anonymous voting
- confidential personal e-health records.

References

Wilson, S. *A novel application of PKI smartcards to anonymise Health Identifiers* AusCERT2005 Security Conference Academic Refereed Stream, Gold Coast, May 2005.

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Acknowledgements

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