

Quality within the EU-FP7 IMPROVED Biobank

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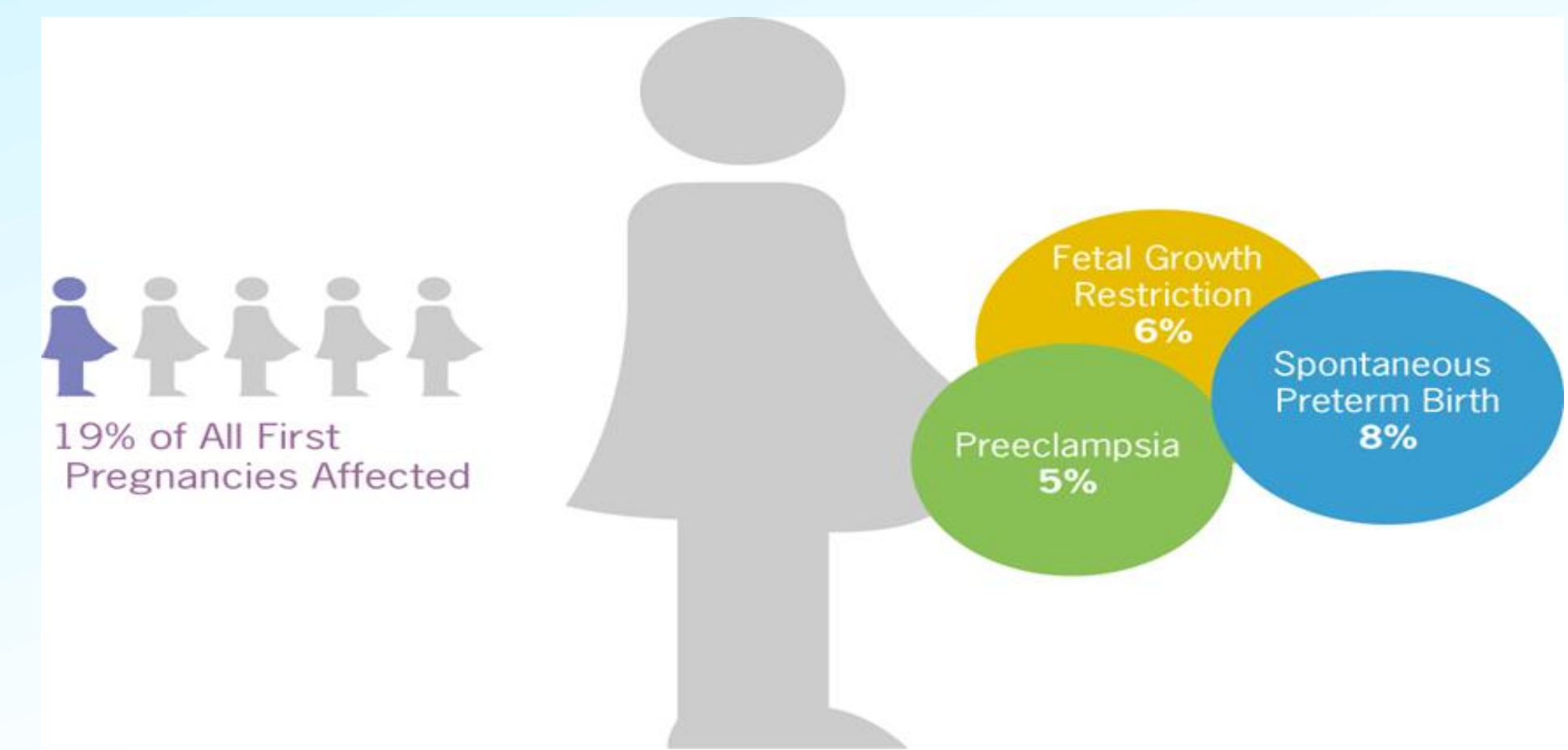
Introduction

A Multicentre Study: The IMPROVED project (IMproved Pregnancy Outcomes by Early Detection) (1) aims to use a personalised medicine strategy to contribute to overall risk prediction of adverse pregnancy outcomes, particularly pre-eclampsia. Six recruitment centres throughout Europe will contribute biological specimens of 5000 nulliparous pregnant women to the EU-FP7 IMPROVED consortium biobank. The blood proteome and metabolome of biospecimens will be mined in a phase II clinical trial using emerging technologies.

Standardisation of Preanalytical Processing in Clinical Sites: The greatest challenge is to establish and maintain a very high calibre biobank, in every aspect from ethics, patient information and consent, use and tracking of data, to specimen to collection and processing, storage infrastructures and shipping criteria for the biospecimens throughout all centres.

Aim: Implementation of a Quality Management System for establishment of the IMPROVED biobank.

Perinatal Disease Burden

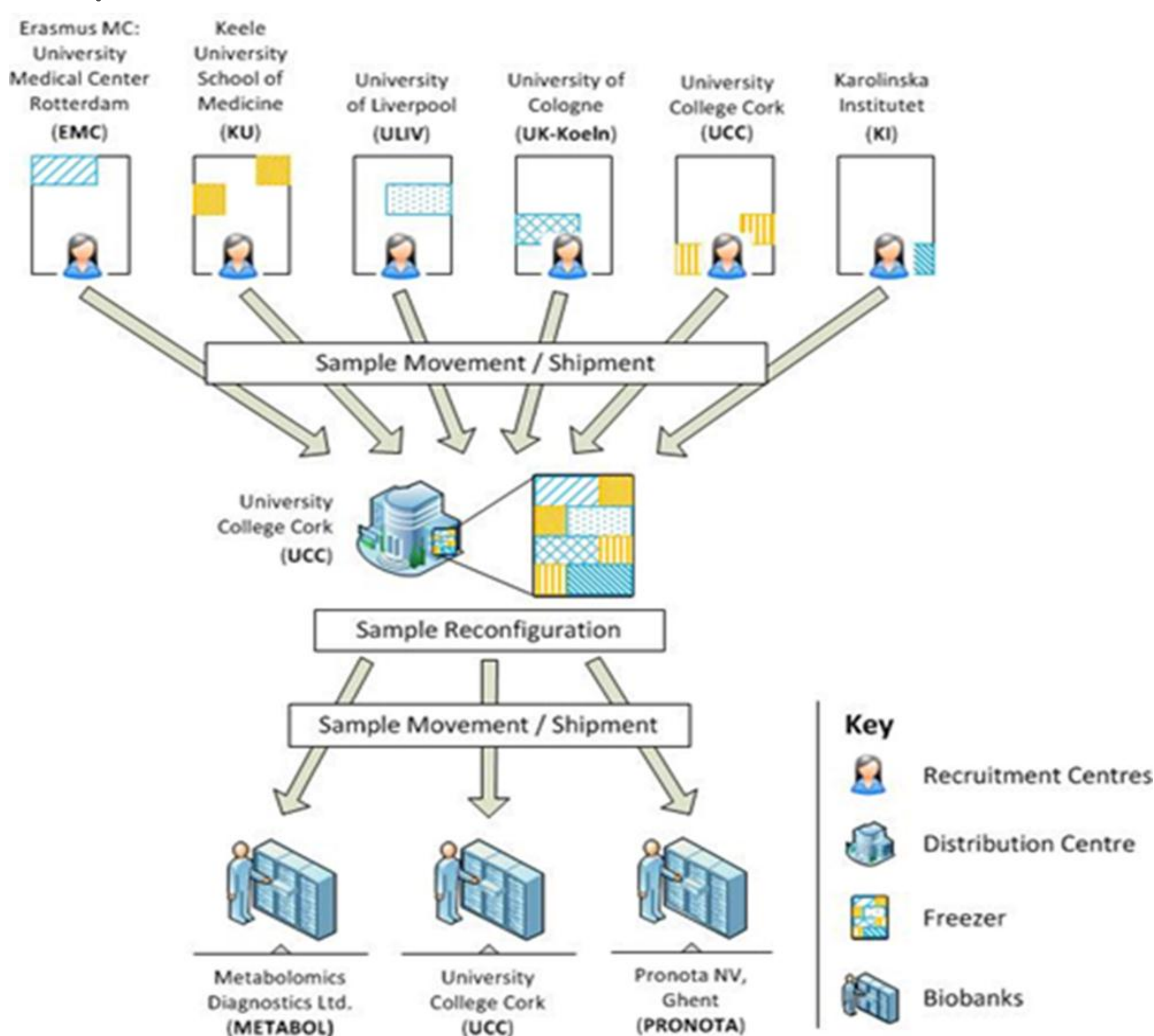


- 500,000 maternal deaths
- 17 cases of significant maternal morbidity for every maternal death
- 3.2 million stillbirths
- 4 million neonatal deaths

Methods and Materials

- Establishment of a Quality Policy and Quality Assurance Plan for all study aspects including ethics, consent, training, biobank establishment, sample movement, data control, clinical trials, reporting.
- Formation of a Quality Committee.
- Adherence to regulatory and international guidelines for biobanking standards including ISBER (2) Guidelines.
- Creation of check lists for risk mitigation to minimize preanalytical variations.
- Establishment of preventative maintenance plans.
- Review documentation management system procedures for study records, deliverables and documents including older versions.
- Review of established pregnancy biobank SOPs, including SCOPE(3) and POPS(4).

Figure 1: Specimen Workflow



Results

- A quality controlled workflow process (Fig. 1) has been established for the management of the IMPROVED pregnancy biobank.
- Use of a customised MedSciNet database (5) (FDA 21 CFR part 11, GCP compliance) to record clinical data, manage sample login, track samples and monitor recruitment and facilitate retrieval of aliquots for case control (randomised) and whole cohort studies and a shipping management module.
- Training, consumables and SOPs for specimen collection and processing have been standardised across all recruitment centres.
- Quality check lists exist for collection centres, reporting, biobanking temperature monitoring and cold storage reserve, sample movement and shipping.
- Sample tracking is facilitated by unique barcodes linking each specimen cryovial to a unique participant number and a unique repository locus within the biobank.
- ULT freezer capacity has been maximised.

Discussion

- Quality assurance activities include: document management, reporting, finances, deliverables, ethics, internal & external audits, corrective and preventative actions.
- The elements of respect for the patient, her data and samples, control of sample quality and specimen security were used to guide workflow process development.
- The key to quality outcomes from the IMPROVED project is the availability of ordered, networked biological resources collected, stored and distributed in a manner to remain as true as possible to the molecular status of the body at time of harvest.
- Prior experiences have informed workflow process and governance of the IMPROVED biobank.

Conclusions

- The IMPROVED Consortium has established a project and biospecimen quality management system to minimize preanalytical variations.
- The pursuit of biobank quality will remain a dynamic activity within the consortium.
- The quality biobank is one of the greatest assets in the IMPROVED consortium.

References

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