

## CLINICAL DATA MODELING FOR NATIONAL SURVEILLANCE OF RARE DISEASES IN JAPAN

**Background:** Japanese ministry of health, labor and welfare has surveyed rare and intractable diseases to research the disease entity and subsidy patients and their families. However, lack of the interoperability of this registry program has been pointed out in these days.

**Objectives:** To improve the interoperability and productivity of this surveillance and to assess the quality of data and care itself.

**Methods:** We examined each clinical research form of six major diseases (ulcerative colitis, primary billiary cirrhosis, systemic lupus erythematosus, polyarthritis nodosa, Perkinsonisms, multiple sclerosis) in specified diseases three categories (digestive disease, autoimmune disease, neurological disease). At first, we figured out the concept on a mindmap to check the variation of term or concept. And the second, we designed templates and archetypes by Ocean Archetype Editor and Ocean Template Designer. which are conformant to ISO/CEN 13606 and openEHR technology.

**Result:** We designed six templates and fifty archetypes for six disease surveillances. For domestic use, health insurance and demographics needed to adjust Japanese conventional style. Clinical knowledge manager provides qualified archetypes for this project, but twenty archetypes were specialised to record disease specific information. One of the most frequent specialisations is to determine severity for each disease and criterion.

**Discussion:** EHR system is expected to be a key role in health care not only in clinical use, but also in research or public health. Therefore, EHR needs semantic interoperability for longitudinal period. ISO 13606 and openEHR technology have been developed as regard to the interoperability of data. The implementation of templates and archetypes improve this intractable disease surveillance quality, even if disease entity is transient in time.

However, we need many archetypes to implement six templates. The clinical knowledge manager provides well-designed archetypes, but they are mainly designed for general practitioner. To diagnosis and manage intractable disease, specialty is necessary and archetypes should include more fields for specialists. Therefore, this experience would enrich the archetype resources for clinical knowledge management.

- TITLES IN CAPITAL LETTERS, **Authors in bolds, Last name and Initials**, Institutions and e-mail in Arial normal size 11 letters. Provide text without free spaces, use international abbreviations or clarify them in the text and respect the space available in the form. The summary must clarify the objectives of the work, the used methods, the results and conclusions.
- The **deadline** for abstracts submission is **December 15<sup>th</sup> 2011**.