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Biotechnology — Data interoperability for stem cell data —

Part_1: Framework

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Foreword

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Introduction

Data interoperability addresses the ability of systems and services that create, exchange and consume data to have clear, shared expectations for the contents, context and meaning of that data.

One-off approaches to data handling and data exchange carry hidden costs for persons and the organizations who are impacted by such data. Most people lack agency when it comes to the data that they generate. Many organizations lack access to the data within their own firewalls. The value of the insights gained from such data is limited because the real potential of such data sets is unrealized.

Stem cell research using human embryonic stem cells (hESC), as well as induced pluripotent stem cells (iPSC) or tissue stem cells, is conducted within ethical and regulatory governance frameworks, which can be highly variable between countries. Stem cells offer unique opportunities to develop therapies for a wide variety of currently intractable conditions. Within this field, it has been recognised that it is premature to focus on any one stem cell type, and that research across a broad front is important to moving the entire field towards application and clinical impact. Furthermore, stem cell research has now reached the stage of clinical testing, with hESC and iPSC-based clinical trials commencing. Moreover, projects provide important 'proof of concept' data for the use of pluripotent stem cell- and tissue stem cell - based therapies in regenerative medicine. Finally, stem cells are becoming a key tool for in vitro disease and tissue modelling, drug and toxicity screening for utilization in the pharma-, chemical-, environmental- and other industries.

In the past decades, research, clinical trials, and industrial developments have greatly increased in scope, diversity and breadth. Moreover, in recent years, many stem cell biobanks have been established. Cross-sector collaborations between academic research institutes, enterprises, governments, industries, etc. [such as Chinese Alliance for Stem Cell Resource Centers, European bank for induced pluripotent stem cells (EBiSC), human pluripotent stem cell registry (PSCreg), International alliance for biological standardization (IABS), International stem cell banking initiative (ISCBI).] have been initiated. Presently, due to the increasing amounts of data associated with stem cell biobanking, it is critical that common approaches to working with data (such as data sharing, storage, analysis, etc.) are standardized. This requires a diverse community of data providers, processors and data consumers to work together and exchange data under same structure and framework. Data interoperability standards aim to help stakeholders and the people who create, manage and use the data to address the shared research requirements and industrial/market needs.