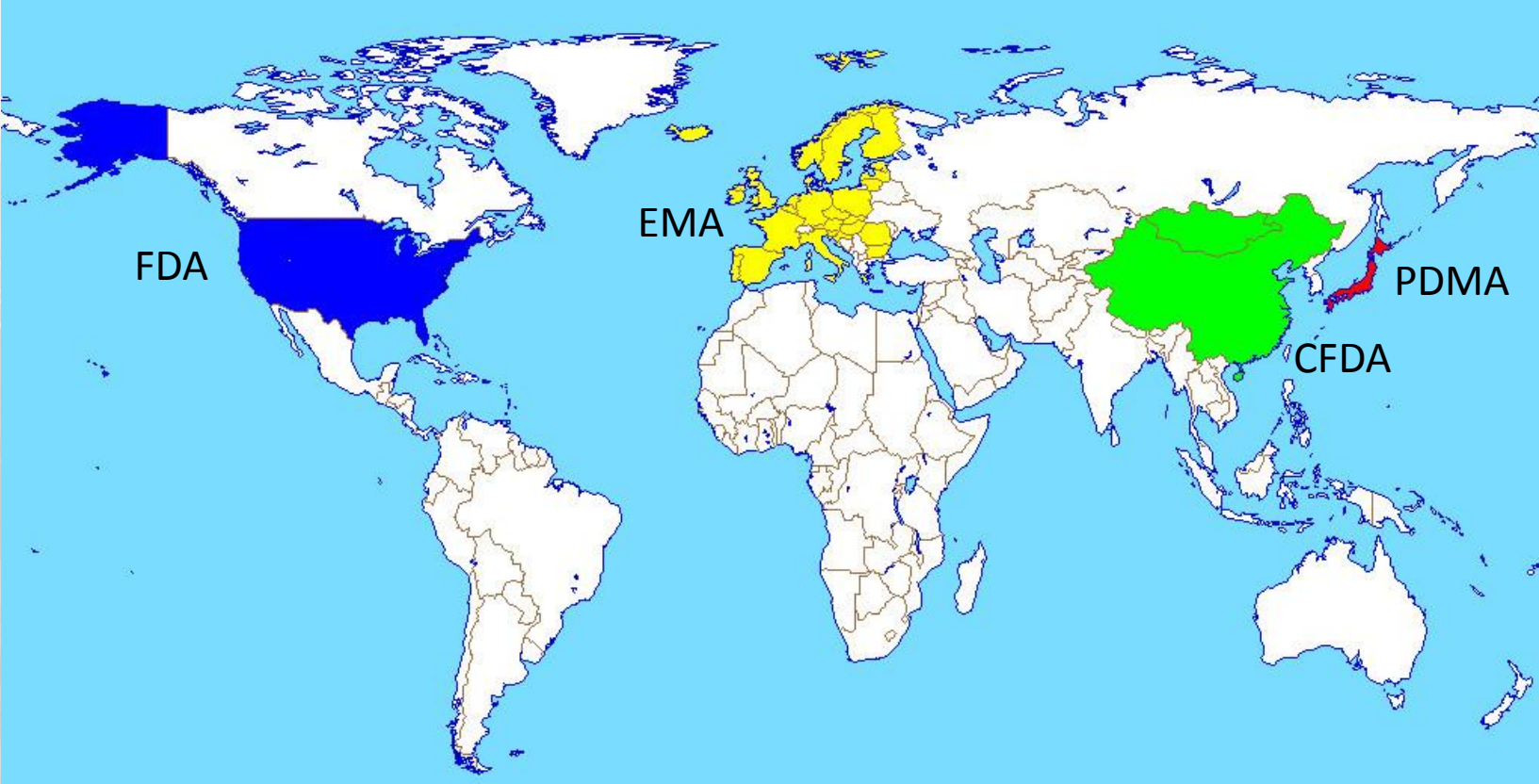Stockholm, September 22nd 2015

Rules, Regulations and Requirements

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Presentation Objectives

- To describe the regulatory environment applicable to the use of electronic data in clinical trials

- To give a current list of relevant regulations, guidelines and requirements in general on the use of electronic data in clinical trials

- To discuss some of the known problem areas and deficiencies with the present regulations regarding the use of electronic data in clinical trials
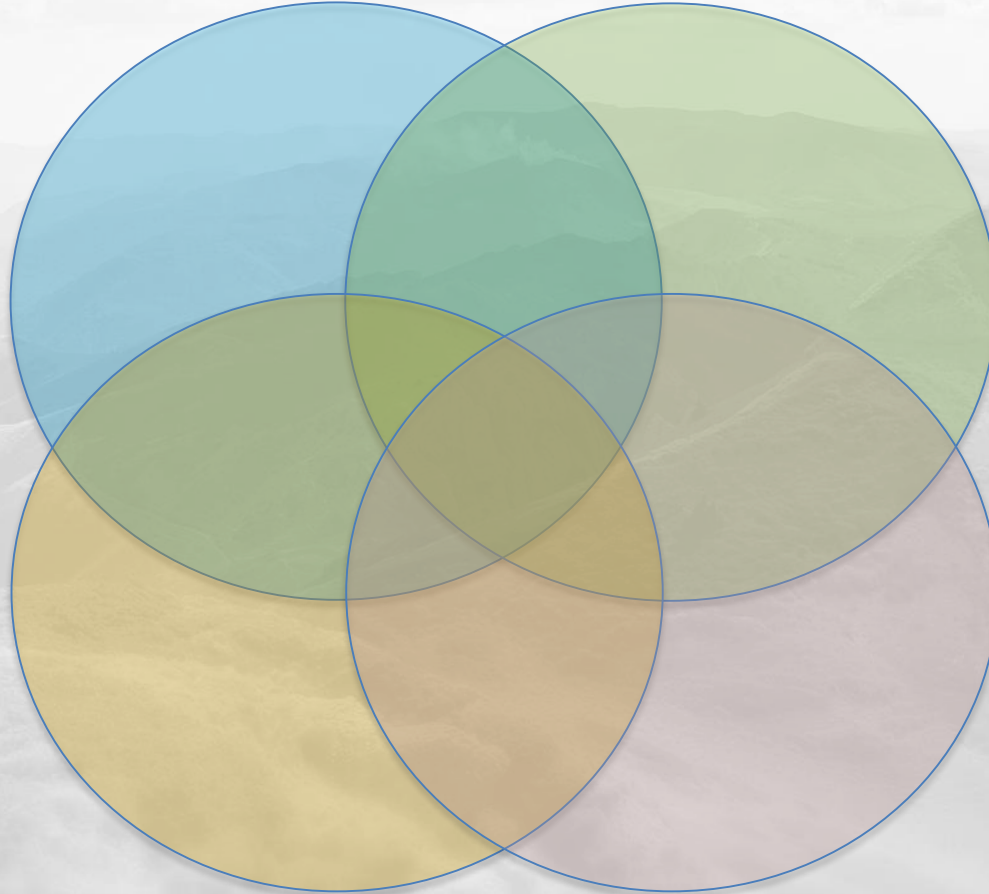
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Regulating Bodies

FDA

EMA

PDMA

CFDA

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Clinical Research Operations

A. ICH E6 Good Clinical Practice (GCP)

B. CFDA – Clinical Trial Data Management Technology Guide

C. EMA – EU Annex 11 – Electronic Records and Electronic Signatures

D. EMA –Reflection paper on expectations for eSource

E. EMA – Reflection paper on risk based quality management in clinical trials

F. FDA – 21 CFR Part 11 Electronic Records ad Electronics Signatures

G. FDA – Computerized Systems Used in Clinical Investigations

H. FDA – Electronic Source Data in Clinical Investigations

I. PDMA – ERES (Electronic Records, Electronic Signatures)

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List of Regulations and Guidelines (2 of 2)

System Development

J. EMA – PIC/S Guidance: Good Practices For Computerised Systems In Regulated "GXP" Environments

K. FDA – GAMP 5 - A Risk-Based Approach to Compliant GxP Computerized Systems
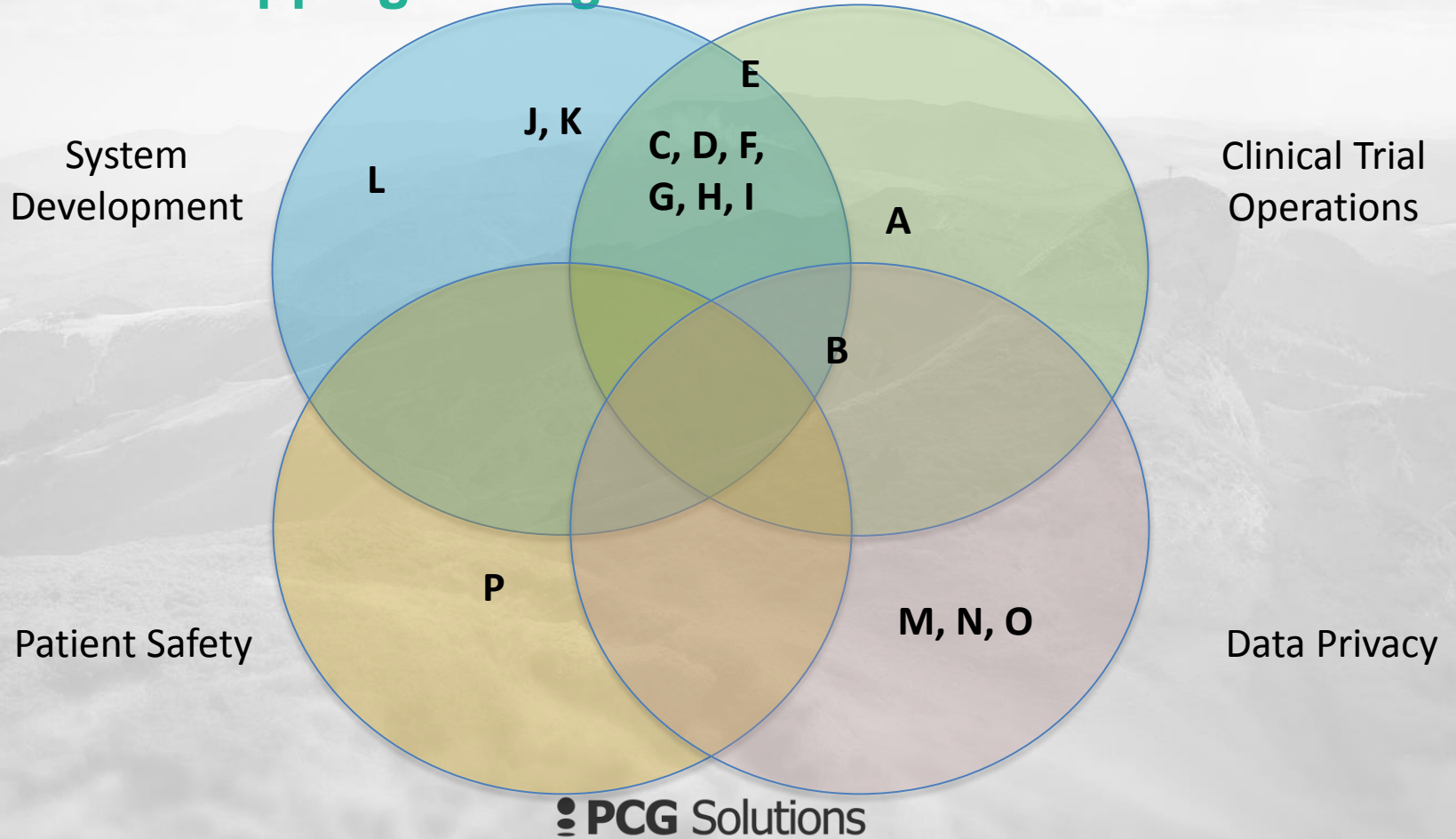
L. FDA – General Principles of Software Validation

Data Privacy

M. EMA – EU Directive 95/46/EC

N. FDA – The Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy, Security and Breach Notification Rules

O. PDMA – Act on the Protection of Personal Information (Act No. 57 of May 30, 2003)

Patient Safety

P. Declaration of Helsinki

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Problem Areas

- Modern development methodologies do not match expectations mentioned in regulatory guidelines:
  - Agile methods, which mean (among other things):
    - No projects
    - No approval of requirements, functional specifications and test cases before implementation starts
- Data privacy:
  - Patients can be identified by 2 people working in concert
  - Patients cannot demand their data be deleted from the CR database (including all backups)
  - Is data stored in Europe subject to European regulations, even if the customer, site, patient, trial and final submission are all to a country outside of Europe (e.g. US or Japan)

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Electronic Data Initiatives

- The eClinical Forum have already performed three initiatives aimed at defining the user requirements on electronic data to be used in clinical trials:
  - The use of electronic data in clinical trials when reusing data from EHR systems (electronic patient journals). Resulted in the international standards "HL7 EHR Functional Model" and the "EuroRec EHR Certification Profile" (2008 – 2010)
  - The assessment of the readiness of sites and systems holding eSource data for use in clinical trials. Resulted in a web-based assessment tool (2013 – 2015)
  - Outsourcing of EDC system operation to Third Party Hosting companies. Will result in a white paper which is being discussed with the EMA GCP IWG, the FDA and other industry associations such as SCDM, EUCROF, RQA, etc. (2014 – 2015)

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REG – a new eClinical Forum Initiative

- Each of the three initiatives mentioned above resulted in a set of User Requirements for the use of electronic data in clinical research

- These User Requirement lists were based on the regulations and guidelines available at those times

- The three User Requirement lists were seen to be general for the use of any kind of electronic data in clinical research (over 95% identical)

- A new working group has been formed to monitor all new and existing regulations, guidelines, Q&A forums, etc. and to refine and maintain the eCF Electronic Data User Requirement list (EDUR)

- The goal is to produce one common list that (if followed) should ensure compliance when using electronic data in clinical research, irrespective of the source of the electronic data

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