ISO 9491-1:2026-06 (E)

Biotechnology - Predictive computational models in personalized medicine research - Part 1: Constructing, verifying and validating models

Contents

Page

Foreword ... **iv**

Introduction ... **v**

1 Scope ... **1**

2 Normative references ... **1**

3 Terms and definitions ... **1**

4 Principles ... **5**

4.1 General ... 5

4.2 Computational models in personalized medicine ... 5

4.2.1 General ... 5

4.2.2 Cellular systems biology models ... 6

4.2.3 Risk prediction for common diseases ... 7

4.2.4 Disease course and therapy response prediction ... 7

4.2.5 Pharmacokinetic/pharmacodynamic modelling and in silico trial simulations ... 8

4.2.6 Artificial intelligence systems (AI systems) ... 8

4.3 Standardization needs for computational models ... 9

4.3.1 General ... 9

4.3.2 Challenges ... 9

4.3.3 Common standards relevant for personalized medicine ... 10

4.4 Data preparation for integration into computer models ... 10

4.4.1 General ... 10

4.4.2 Pre-examination data ... 11

4.4.3 Data formatting ... 12

4.4.4 Data description ... 13

4.4.5 Data annotation (semantics) ... 13

4.4.6 Data interoperability requirements across subdomains ... 14

4.4.7 Data integration ... 15

4.4.8 Data provenance information ... 15

4.4.9 Data access ... 16

4.5 Model formatting ... 16

4.6 Model validation ... 17

4.6.1 General ... 17

4.6.2 Specific recommendations for model validation ... 17

4.7 Model simulation ... 19

4.7.1 General ... 19

4.7.2 Requirements for capturing and sharing simulation set-ups ... 20

4.7.3 Requirements for capturing and sharing simulation results ... 20

4.8 Requirements for model storing and sharing ... 20

4.9 Application of models in clinical trials and research ... 21

4.9.1 General ... 21

4.9.2 Specific recommendations ... 21

4.10 Ethical requirements for modelling in personalized medicine ... 21

Annex A (informative) **Common standards relevant for personalized medicine and in silico approaches** ... **23**

Annex B (informative) **Information on modelling approaches relevant for personalized medicine** ... **26**

Bibliography ... **28**