# Supplementary Material

## IMDRF member jurisdictions

Table S.1: Regulatory authorities' websites for IMDRF member jurisdictions

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| **Jurisdiction** | **Regulatory Authority** | **Website** |
| Australia | *Therapeutic Goods Administration (TGA)* | <https://www.tga.gov.au/> |
| Brazil | *Agência Nacional de Vigilância Sanitária (ANVISA)* | <http://portal.anvisa.gov.br/english> |
| Canada | *Medical Devices Bureau (MDB)* | <https://www.canada.ca/en/health-canada/corporate/about-health-canada/branches-agencies/health-products-food-branch/therapeutic-products-directorate.html> |
| China | *China Food and Drug Administration (CFDA)* | <http://eng.sfda.gov.cn/WS03/CL0755/> |
| European Economic Area (EEA) | *European Commission* | <https://ec.europa.eu/commission/index_en> |
| Japan | *Pharmaceutical and Medical Device Agency (PMDA)* | <https://www.pmda.go.jp/english/> |
| Russia | *Roszdravnadzor (Federal Service for Surveillance in Healthcare)* | <http://www.roszdravnadzor.ru/en/> |
| Singapore | *Health Sciences Authority (HSA)* | [www.hsa.gov.sg](http://www.hsa.gov.sg) |
| Republic of Korea (South) | *Ministry of Food and Drug Safety (MFDS)* | <http://www.mfds.go.kr/eng/index.do> |
| United States of America (USA)a | *U.S. Food and Drug Administration (FDA)* | <https://www.fda.gov/> |

**Explanatory note:**

**a** The FDA was directly contacted in April 2018 to clarify what regulations applied to medical apps, due agency being in a period of policy reform.(54)

## Sources of data extraction form

The data extraction form also incorporated elements from the IMDRF guidance document *SaMD: Possible Framework for Risk Categorization and Corresponding Considerations(9)*  when these details were referenced in the *SaMD: Clinical Evaluation(13)*. The data extraction form excluded recommendations relating to the IMDRF guidance document *SaMD: Application of Quality Management Systems(16)* as these were not health system specific considerations.