**Appendix 2 – Examples of activities on the Technology Readiness Level (TRL)**

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| **TRL** |  **TECHNOLOGY AREAS/FIELDS**  |
| **Medical/Device** | **Diagnostic Tools/Digital Health** | **Other** |
| **1** | Discovery research with potential application addressing a medical need. |
| **2** | Scientific review and generation of research ideas, hypotheses, and experimental designs |
| **3** | Development of a functional prototype through to demonstration of proof-of-concept efficacy for device in vitro and in vivo | Biomarker quantification studies through to establishing specificity of biomarkers using clinical samples | Development of a functional prototype through to demonstration of proof of-concept in vitro and in vivo or in a test set |
| **4** | Efficacy and safety of candidate devices demonstrated in defined laboratory or animal models (non GLP) | Retrospective and prospective biomarker qualification studies complete, or analytical parameters acquired and optimized | Proof-of-concept demonstrated to pre regulatory standard |
| **5** | Safety and toxicity established to GLP standards (in animal models) and manufacturing process established at the required scale | Assay suited to target clinical setting has been developed and manufacturing process established at the required scale | Regulatory Characterization of Product and Initiation of Process Development or Manufacturing Process Prior to Clinical Trials |
| **6** | Phase I or equivalent studies in humans to assess device safety [to completion] | Usability of tools has been established with end user groups in situ or assay parameters have been established with clinical samples [to completion] | Clinical Refinement: Phase I or equivalent studies in humans to assess device safety [to completion] |
| **7** | Phase II or equivalent studies to assess efficacy and performance [to completion] | Small-scale or single site evaluation of whether the application of the diagnostic improves clinical outcomes complete [to completion] | Early Clinical Assessment: Phase II or equivalent studies to assess efficacy and performance [to completion] |
| **8** | Phase III or equivalent studies and Market Authorization and CE marking complete | Multi-site evaluation of whether the tool improves outcomes complete. Market Authorization / CE marking achieved | Late ClinicalEvaluation/Market Authorization |