This document contains information and guidance to assist users in selecting the appropriate ‘type’ when reporting a medical product or intervention. This guidance is provided and governed by the funders that subscribe to Researchfish.

Please direct any questions to support@researchfish.com.
Drug / Medical Device: Assess safety in healthy volunteer group / patient group, where appropriate
Support Tool: Establish usability with user group
Diagnostic Tool: Establish assay parameters on clinical samples
Psychotherapeutic Intervention: Test intervention package in volunteer group for acceptability

Drug: Is there sufficient proof of mechanism?
Support Tool / Medical Device: Is there a breadboard prototype and is it sufficiently capable of meeting the targeted need?
Diagnostic Tool: Is the sensitivity and specificity of the biomarkers expected to be sufficient?
Psychotherapeutic Intervention: Are the underlying psychological causative factors and/or associated factors sufficiently understood?

Drug: Hit identification and Lead Optimization, including early liability assessment
Support Tool / Medical Device: Develop functional prototype
Diagnostic Tool: Undertake retrospective and prospective biomarker qualification studies. In the case of imaging applications, the optimization of acquisition and analytic parameters in preclinical or Phase 0 setting
Psychotherapeutic Intervention: Development of manual

Drug / Medical Device: Is there good animal proof of concept?
Support Tool: Is there sufficient evidence that the functional prototype can meet the targeted need
Diagnostic Tool: Do the biomarkers have sufficient sensitivity and specificity in a prospective clinical study?
Psychotherapeutic Intervention: Is there sufficient evidence that the manual is likely to work?

Drug / Medical Device: Establish manufacture process at required scale / tolerance and assess safety in animal models
Support Tool: Establish manufacture / distribution process at required scale / tolerance
Diagnostic Tool: Develop assay suited to target clinical setting
Psychotherapeutic Intervention: Develop intervention package (e.g. hardware (pamphlets, etc) / software)

Drug / Medical Device: Can intervention reach target site within acceptable safety margins?
Support Tool: Does tool offer acceptable ease of use and can it be supplied to end users at required speed / quality / quality?
Diagnostic Tool: Does the assay meet performance requirements?
Psychotherapeutic Intervention: Has intervention package passed User Acceptability Testing in healthy volunteer group?

Drug / Medical Device: Phase II or equivalent studies to assess efficacy / performance
Support Tool: Small-scale user testing
Diagnostic Tool: Small-scale, single site assessment of whether use of the tool in target clinical setting improves clinical outcome
Psychotherapeutic Intervention: Small-scale, often single-site, assessment of protocol in small number of patients

Drug / Medical Device: Phase III or equivalent studies
Support Tool: Large-scale user testing
Diagnostic Tool: Multi-site evaluation of whether use of the tool in target clinical setting improves clinical outcome
Psychotherapeutic Intervention: Multi-site evaluation of protocol in large number of patients

Drug: e.g. Regulatory body authorization
Medical Device: e.g. CE marking
Support Tool: e.g. CE marking
Diagnostic Tool: e.g. CE marking

Adopted by a small proportion of potential users, perhaps due to recent launch
Adopted by a large proportion of potential users