CRF-UCC
HRB Clinical Research Facility University College Cork

International Clinical Trials Day 2023

Dr Brendan Palmer

Statistics, Data & Analysis Unit




Supporting academic-led clinical research

Academic Funding Application Support

Access to Clinical Research Infrastructure

Clinical Trial Design

Study Design, Data, and Statistical Support

FAIR Data Management and Stewardship

Compliance with General Data Protection Regulations

Quality and Regulatory affairs

Research Budgets

Systematic Reviews

PPI in Clinical Research

Project Management

Studies Within A Trial (SWAT)

The winds of change

Written on Nov 22, 2017.

The Open Research Data Pilot of the European Commission enables open access and reuse of research data generated by Horizon 2020 projects. There are two main pillars to the Pilot: developing a Data Management Plan (DMP) and providing open access to research data, if possible.

The conditions you have to adhere to, are:

- Develop (and keep up-to-date) a Data Management Plan (DMP).
- Deposit your data in a research data repository.
- Ensure third parties can freely access, mine, exploit, reproduce and disseminate your data.
- Provide related information and identify (or provide) the tools needed to use the raw data to validate your research.

The Pilot applies to:

- The data (and metadata) needed to validate results in scientific publications.
- Other curated and/or raw data (and metadata) that you specify in the DMP.

Data management costs are eligible for reimbursement during the duration of the project, and can be claimed under the conditions defined in the grant agreement.

The winds of change

OpenAIRE

Services Support Open Science In Europe About SIGN IN

What are the requirements?

Proper Research Data Management (RDM) is mandatory for any Horizon Europe project generating or reusing research data.
It is a key part of Horizon Europe's open science requirements.

In Horizon Europe, *beneficiaries must manage the digital research data generated in the action ('data') responsibly, in line with the* ***FAIR principles***, and should at least do the following:

- Prepare a Data Management Plan (DMP) and keep it updated throughout the course of the project
- Deposit data in a trusted repository and provide open access to it ('as open as possible, as closed as necessary')
- Provide information (via the same repository) about any research output or any other tools and instruments needed to re-use or validate the data

Keep in mind that 'research data' is a very broad concept and certainly not limited to numerical/tabular data.

The winds of change apply to you

HRB Health Research Board

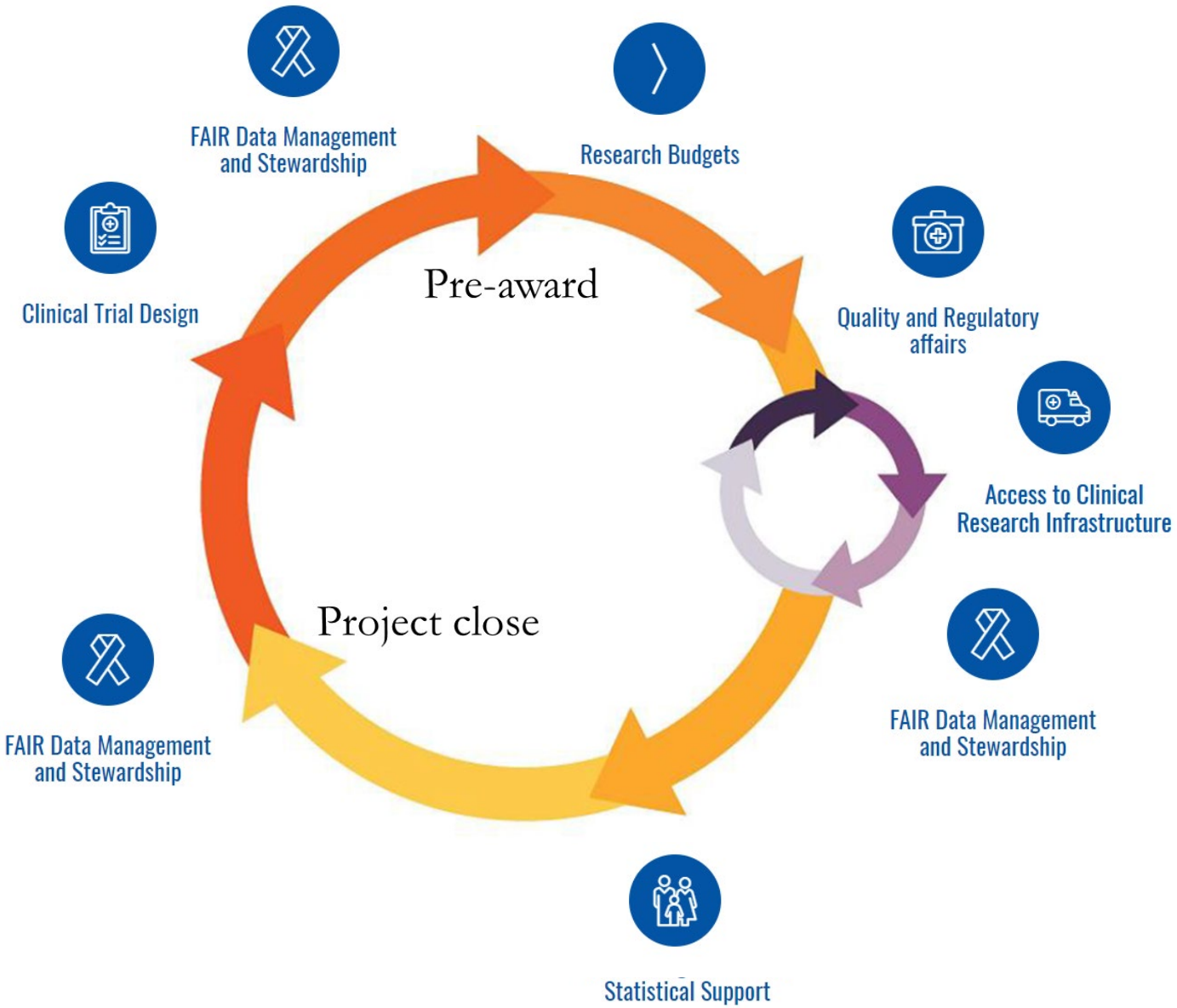
HRB Policy on Management and Sharing of Research Data

For data gathered and generated in whole or in part from HRB-funded research, the following policy will be adhered to with effect from 1st of January 2020.

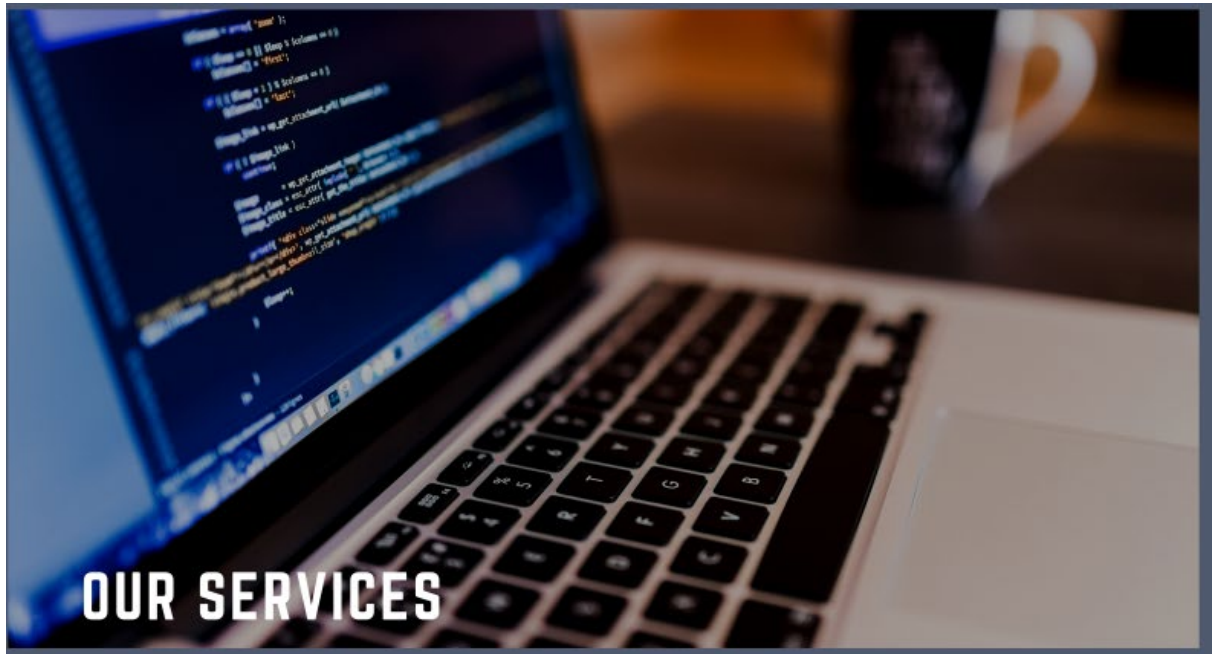
Introduction

The Health Research Board (HRB) supports and promotes research that will improve people's health, patient care and health service delivery. The primary output from the research projects funded by the HRB is often the data gathered and generated to support observations and validate the project. To ensure that this data is used to its maximum potential, data needs to be adequately managed from the earliest stage in the research process and should be preserved and made available for reuse beyond the original project.

Research lifecycle engagement with the CRF-UCC



Statistics, Data & Analysis Unit (SDAU)



OUR SERVICES

GRANT DEVELOPMENT

We supply *pro bono* supports to help with external grant applications by providing expert advice on study design, protocol development, statistical analysis plans, data management plans and relevant research regulations.

DATA MANAGEMENT PLANS

We can help you develop your data management plan, ensuring that you meet funder, legal and regulatory requirements and appropriately budget for data management needs.

STATISTICAL ANALYSIS

We can help you design your study, develop statistical analysis plans, analyse the study data and report results.

ELECTRONIC DATA CAPTURE

We can design, deploy and maintain electronic data capture platforms for patient focused studies, including regulated clinical trials.

FAIR DATA

We can ensure that your research data are Findable, Accessible, Interoperable, and Reusable at the end of your study, in line with both funder and publisher requirements.

OPEN RESEARCH METHODS

We use Open Research practices where FAIR data, analysis code and reports are all produced from a cohesive, transparent, reproducible workflow.

OUR PEOPLE

Dr Darren Dahly is the CRF-UCC Principal Statistician and leads the SDAU. He has been in this role since 2015. He is also a member of the Irish National Research Ethics Committee for Clinical Trials, the MRC/NIHR Trials Methodology Research Partnership, and a Senior Lecturer in Patient Focused Research Methods in the UCC School of Public Health.

Dr Brendan Palmer is the Manager of Research Data Services with the CRF-UCC and a HRB Data Steward. Brendan has been involved in a variety of Open Science initiatives, including the development of the HRB's approach to FAIR data stewardship and the establishment of an Irish national data steward network.

Christine Allan is a Research Data Manager with the CRF-UCC and is responsible for the design, deployment and maintenance of electronic data capture systems available to the studies we work with and works alongside researchers to ensure their study's data management needs are met.

LYSA - Linking You to Support and Advice

Primary Objective

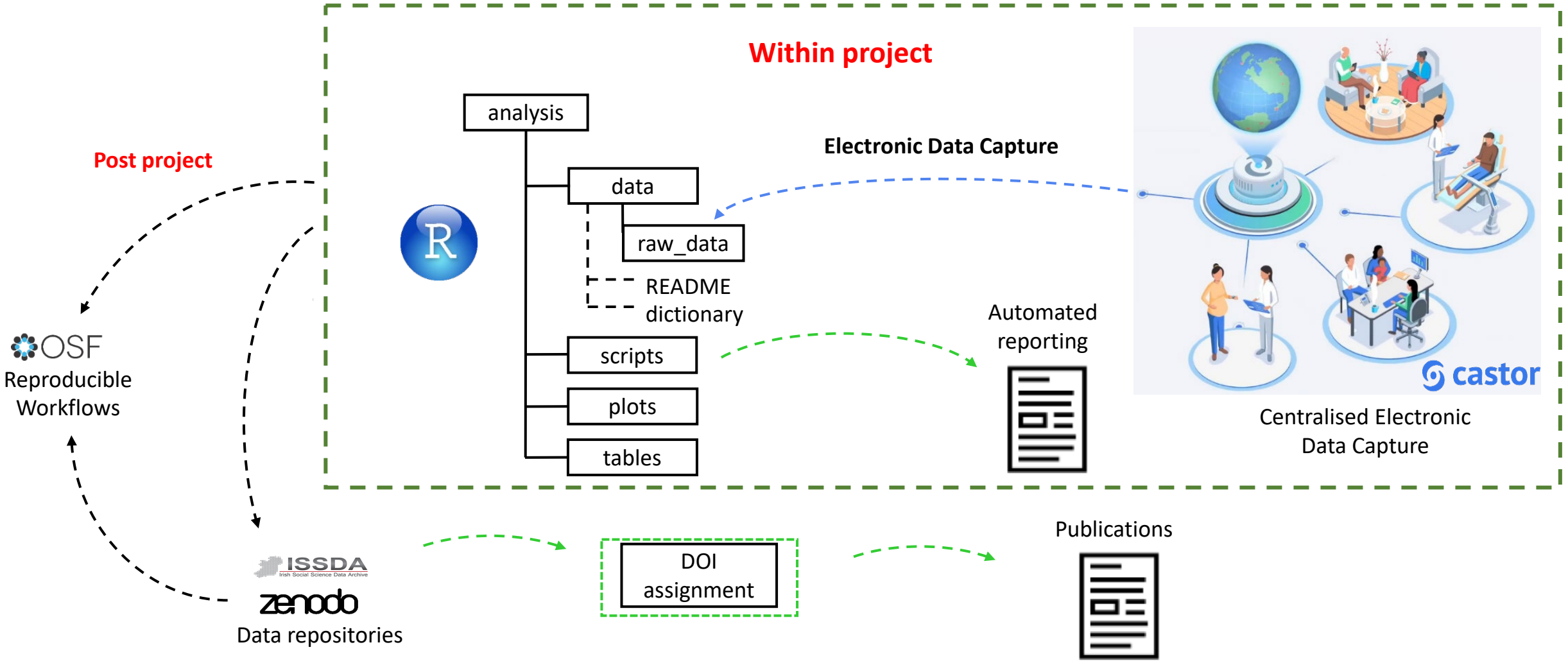
To evaluate the feasibility of introducing a women's malignancy survivorship clinic incorporating **symptom management through ePRO collection** into routine follow up care in patients with early stage HR positive breast and gynaecologic cancer post primary therapy

Secondary Objectives

- Patient and clinic satisfaction
- Impact dietetic intervention
- Explore self-care agency
- Describe symptoms
- Resource and economic impact
- Evaluate endocrine therapy adherence

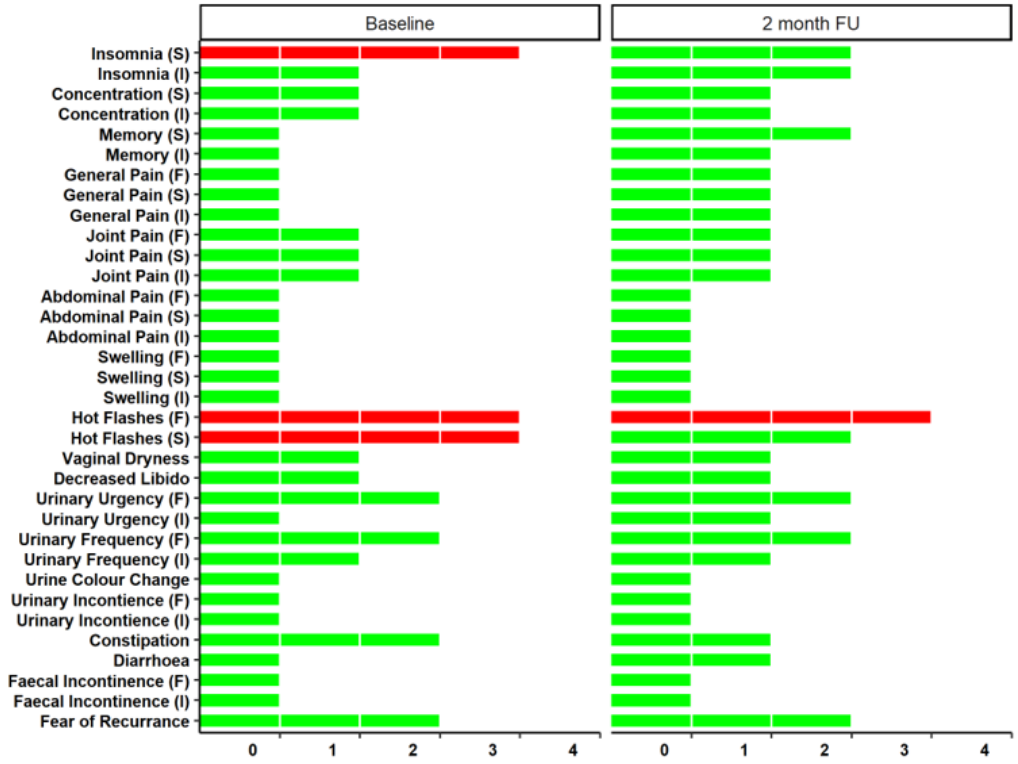
Irish Cancer Society | Women's Health Initiative | breakthrough CANCER RESEARCH

End-to-end supports that are reproducible



LYSA - the benefits of embedded supports

PRO-CTCAE Symptoms

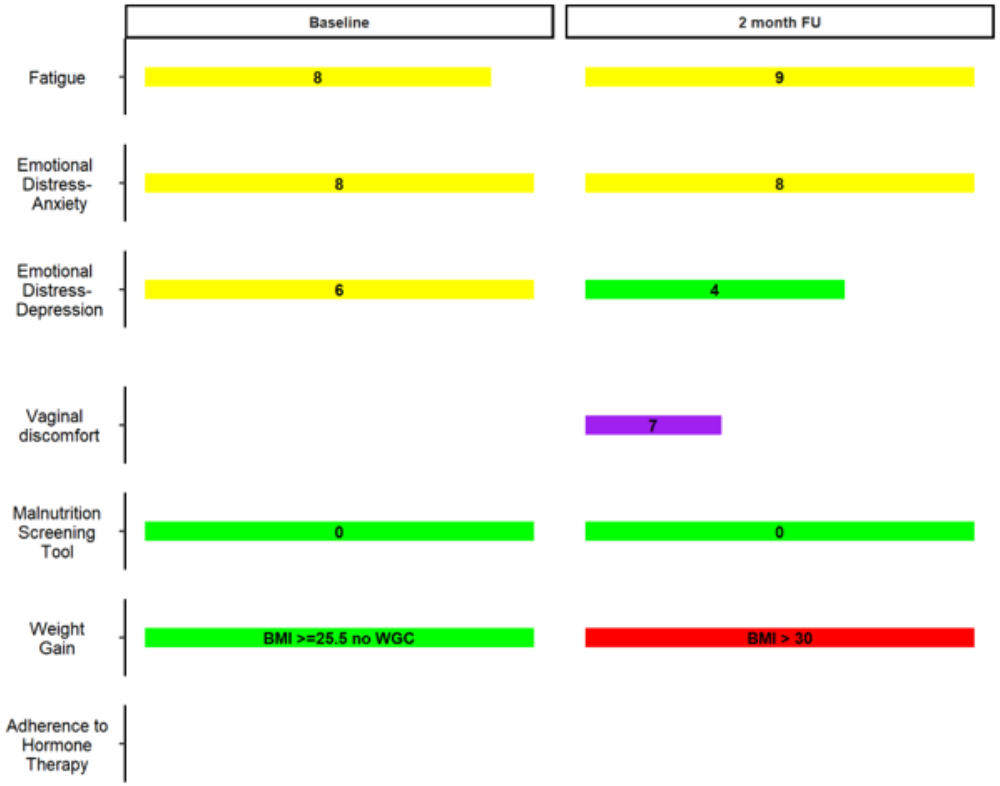


Red for scores >= 3

Purple for increases <= 2 points when baseline reading was zero

Scale runs from 0-4

Additional Triggers and Scores



Fatigue: 0-4/green, 5-11/yellow, 12-18/orange, 5 or more greater than baseline/purple, >18/red

Emotional distress-anxiety: 0-4/red, 5-11/yellow, 12-15/orange, 5 or more greater than baseline/purple, >15 red

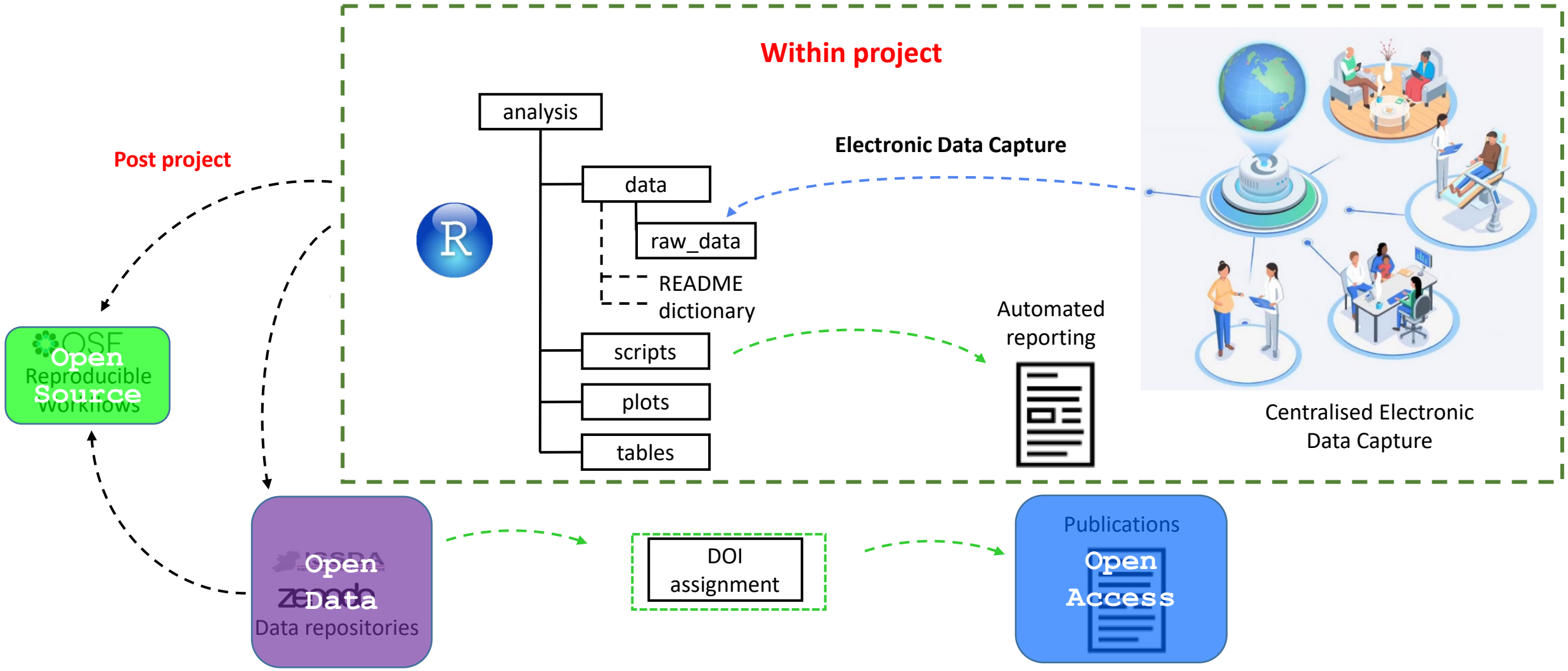
Emotional distress-depression: 0-4/red, 5-11/yellow, 12-16/orange, 5 or more greater than baseline/purple, >16 red

Vaginal discomfort: 0-5/green, 6-10/yellow, 11-13/orange, 5 or more greater than baseline/purple, 14/red

MST: 0-1/green, 2-7/red

Weight gain: BMI < 25.5 or BMI >=25.5 + no WGC/green, BMI >=25.5 + WGC/unsure or BMI > 30/red

End-to-end supports that are open



Supporting research that benefits wider society

in4kids
Irish Network for Children's Clinical Research

ctg
UCC CANCER TRIALS GROUP

OPTIMATE

CoARA

Tyndall
National Institute
Institiúid Náisiúnta

E-MAT
Enhancing Men's Awareness of Testicular Diseases

hpsc

HRB
Health Research Board

apc Microbiome Ireland

Irish Cancer Society

NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

HSE

Infant
Irish Centre for Fetal and Neonatal Translational Research

Liam Mc Trial
Supporting men through cancer

PROSPERH

NORF
NATIONAL OPEN RESEARCH FORUM