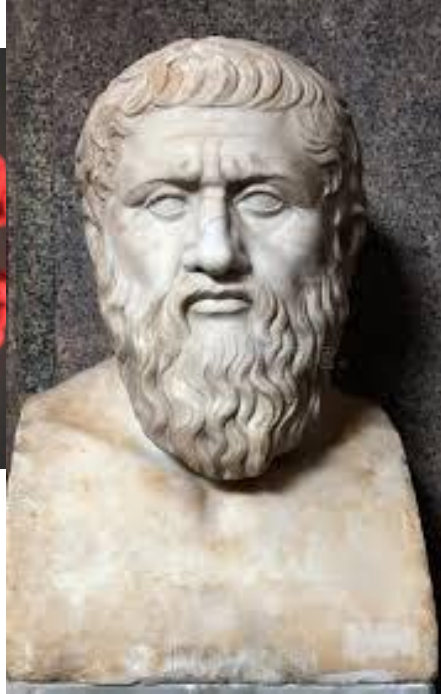
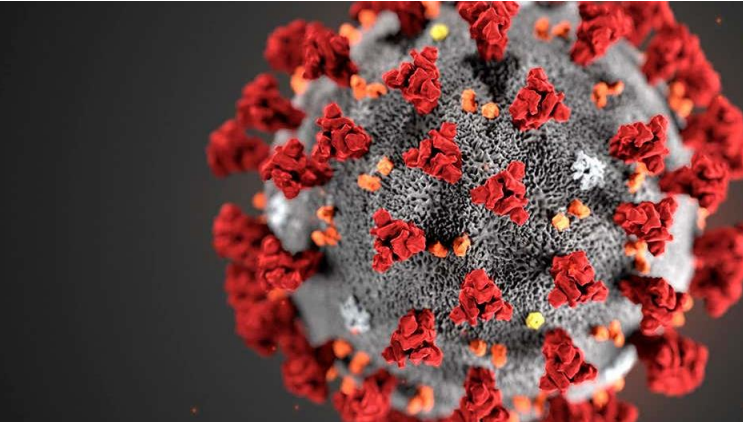


IDEAL Update: What to do in a crisis?



Peter McCulloch
Chair, IDEAL Collaboration



Agenda

1 What IDEAL is

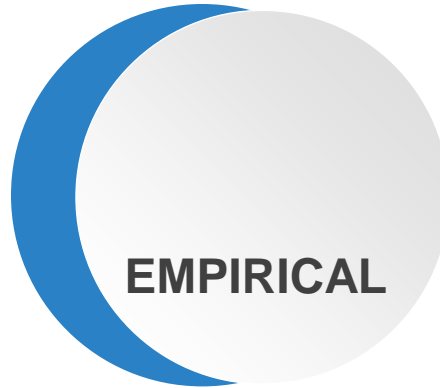
2 What IDEAL has been doing

3 The challenge of evaluation in a crisis:
Covid 19 and IDEAL in urgent situations

Foundations of IDEAL



*Founded on 4
principles of medical
ethics*



*Developed by analysing
the life-cycle of complex
therapies*



*Links Innovation with
Evaluation at every
stage*

An Integrated Evaluation Pathway

REGISTRATION OF 1st in MAN
(Stage 1)



PROSPECTIVE DEVELOPMENT STUDY
(Stage 2a)



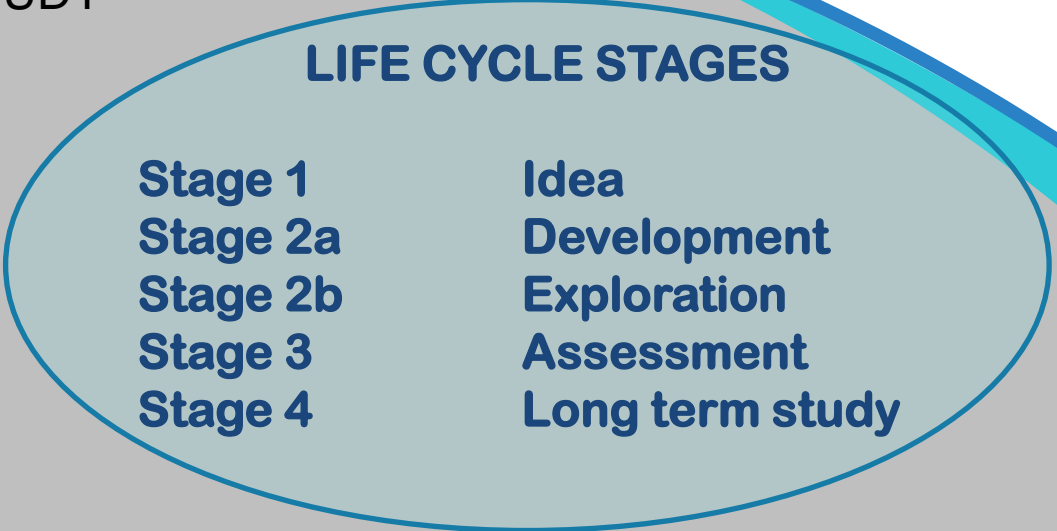
PROSPECTIVE EXPLORATION STUDY
(Stage 2b)



RCT (Stage 3)



REGISTRY (Stage 4)



Novel Recommendations

- ❖ Registry for first-in-man with protection against legal discovery (Stage 1)
- ❖ Description of iterative innovation process and its outcomes (Stage 2a)
- ❖ Pooling and discussion of data to reach consensus and define controversy (Stage 2b)
- ❖ RCTs with measures to improve equipoise (Stage 3)
- ❖ Clear understanding of real world evidence value (Stage 4)

Evolution & Application

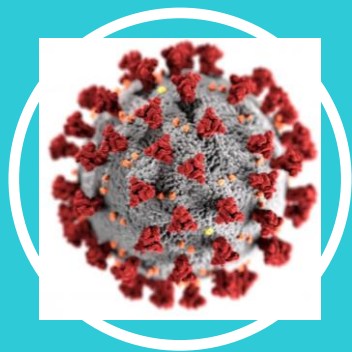
EVOLUTION

- a. Crystallisation of Recommendations – principles to specifics*
- b. Modification for Devices Physio & Radiotherapy*
- c. Development of Stage 0 recommendations€
- d. Integration of RWE into IDEAL paradigm €

APPLICATION

- a. Alignment with medical device regulations €
- b. When not to do an RCT €
- c. How to evaluate surgical robots
- d. Evaluation in emergencies





Covid 19

A real crisis.

IDEAL and Evaluation in Crisis:

IDEAL - up to a point



First Time: IDEAL Stage 1

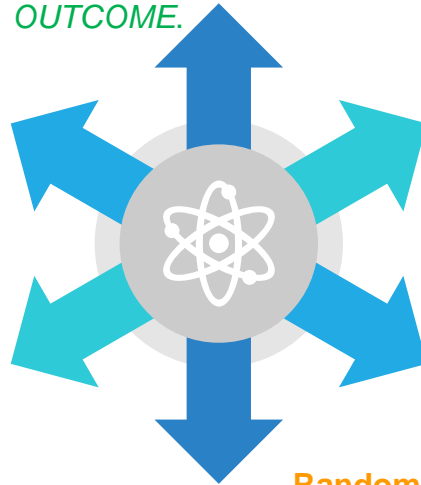
Full transparency and detailed description of WHAT, WHY, HOW and with WHAT OUTCOME.

Big numbers for monitoring: IDEAL Stage 4

Use Real World Data intelligently

**Are we still improving?
Can we justify it?**

Would we do better to carry on iterating?.



Learning by doing: IDEAL Stage 2a

Record each case sequentially, with all changes, detailing WHAT, WHY and with WHAT OUTCOME

Pooling data & discussion: IDEAL 2b

Share experience and pool data to accumulate numbers: discuss variability and define consensus

Randomise or carry on? IDEAL Stage 3

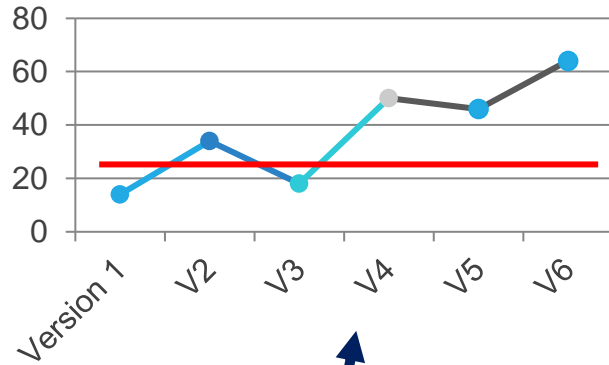
When is it right to allocate controls?

Judgement of Solomon

- **Randomise to die?**
- **Treat our consciences and abandon the chance to know the truth for next time**



Innovation & Iteration



IDEAL 2a like chart

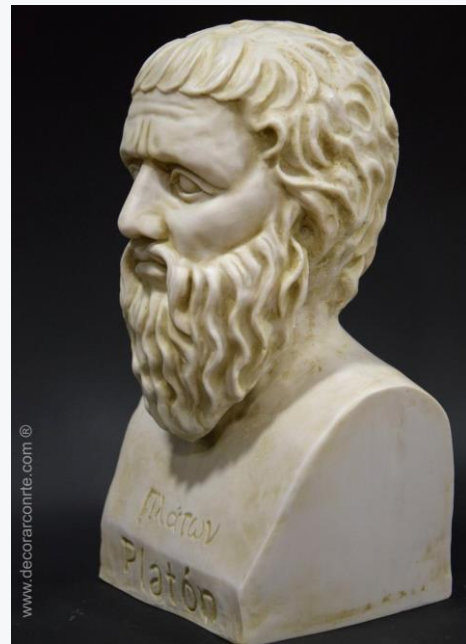
Its OK to use QI methods to develop something new IF:

- You start by checking it looks good
- You go on checking if its getting better

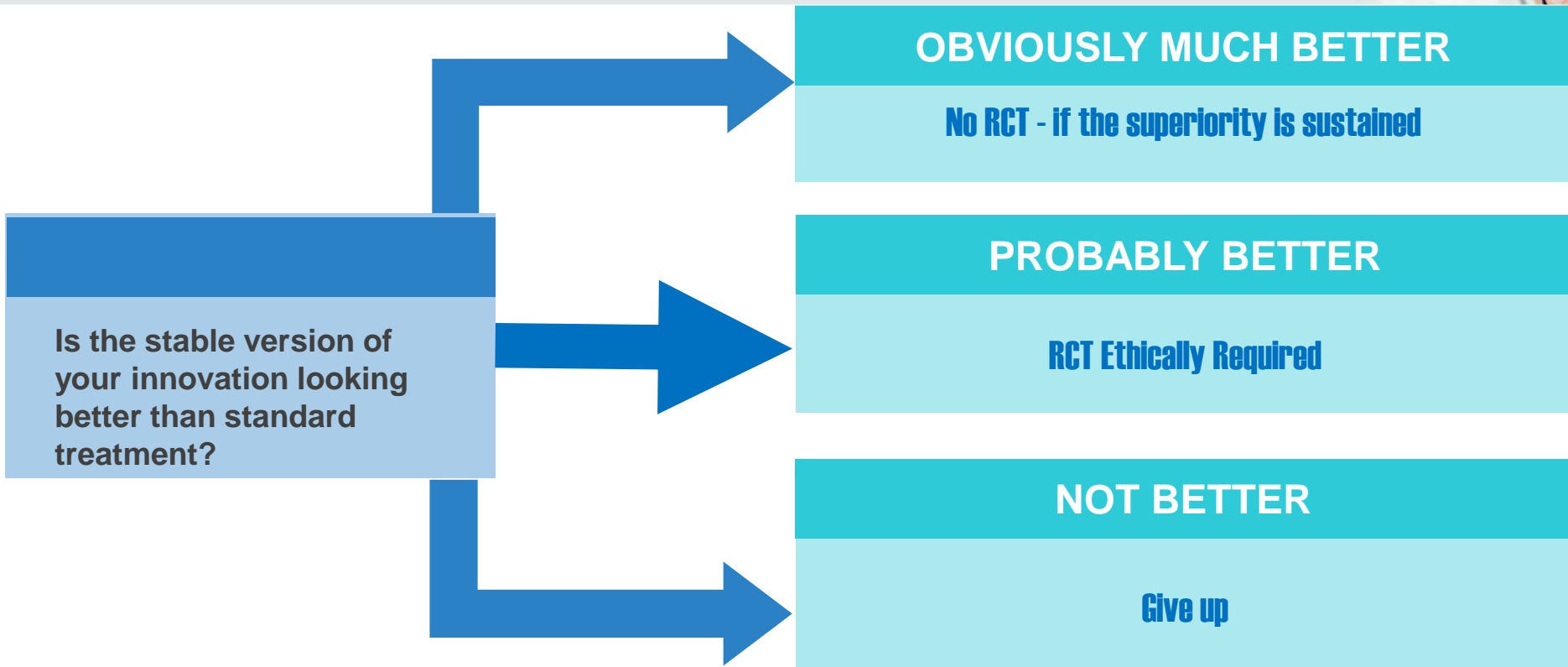
BUT What happens when you can't improve more?

Sharing and Agreeing

- ❖ Data pooling and discussion promotes consensus and clarifies controversial points
- ❖ Large numbers improve effect estimate precision and reduce regression to mean effects
- ❖ *This is implementation of IDEAL Stage 2b*



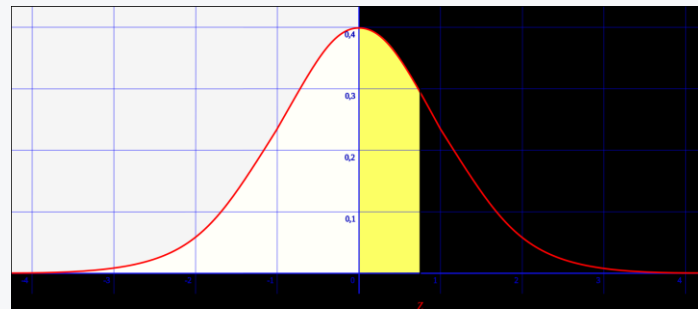
Decision Tree



What do we mean by..?

- ❖ **OBVIOUSLY MUCH BETTER:** More than twice as effective (HR>2)
- ❖ **PROBABLY BETTER:** At least 50% chance of being better (mean outcome >0.69 SD higher than control mean)

Need to show consistency to exclude regression to the mean



Common Sense is always helpful!

Getting the System Right

- a. Collaborate don't compete
- b. Repurpose available data & resources
- c. Streamlined fused review process with pro-active facilitation
- c. Target **what is needed**
- d. Do NOT offer blank cheque competitions!





Thank you



IDEAL TimeLine



Initial Lancet papers describing IDEAL.

2009

BMJ series describing stages of IDEAL

2012

IDEAL-D paper outlining modifications for using IDEAL with medical devices.

2016

Revised IDEAL Recommendations.

2018

IDEAL Reporting Guidelines (in press).

2020

