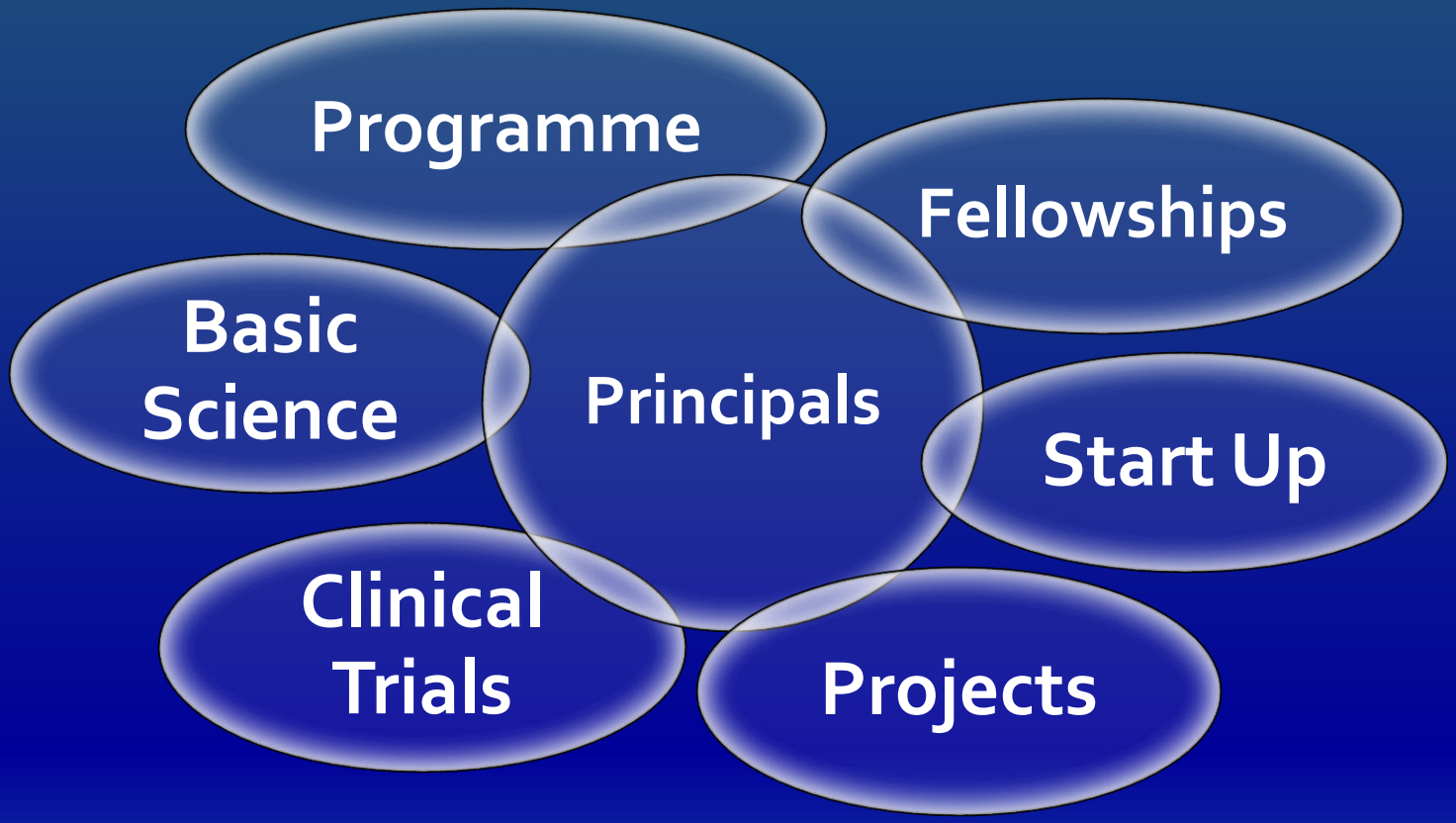
How to write a grant application

International Course in Paediatric Research

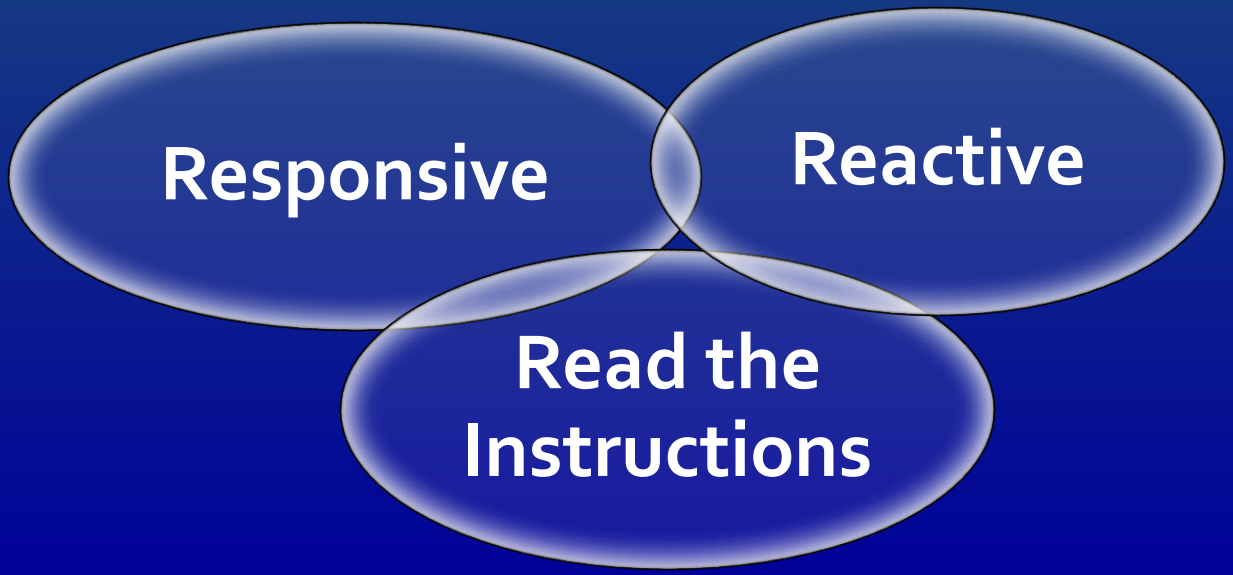
Chieti 2015

Prof. D. B. Dunger

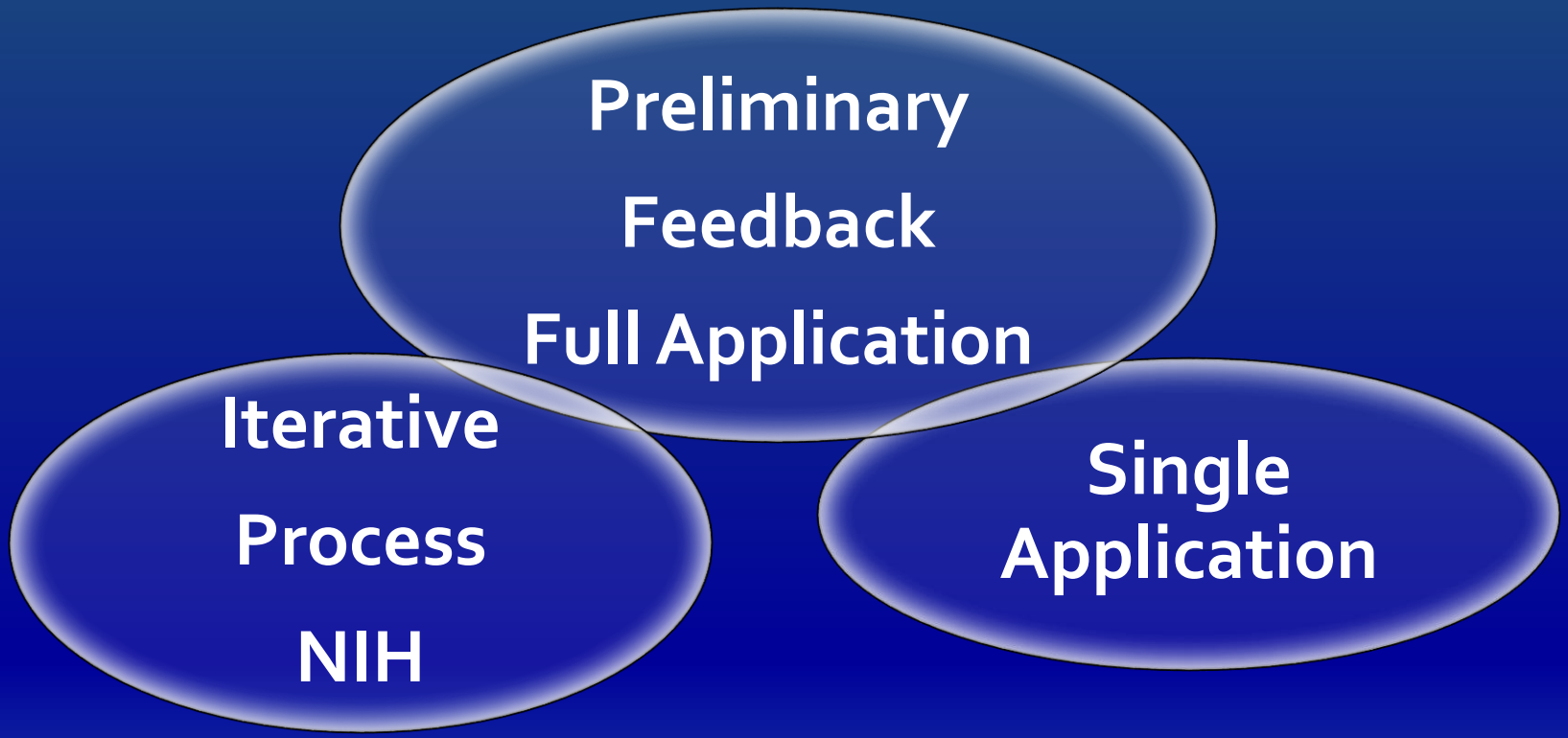
Types of Grants



Types of Grants

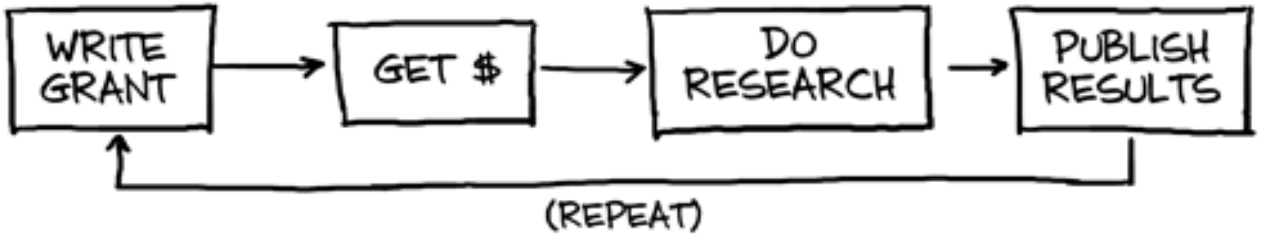


Process


Preliminary
Feedback
Full Application
Iterative
Process
NIH
Single
Application

THE GRANT CYCLE

HOW IT'S SUPPOSED TO WORK:



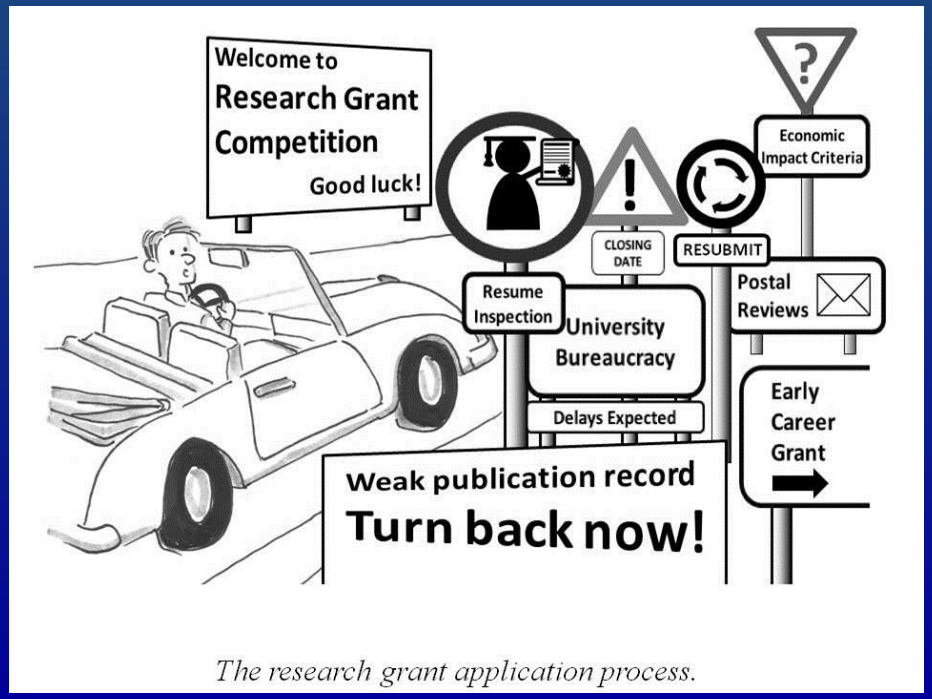
HOW IT REALLY WORKS:


PAPER
ACCEPTED!

The Review Panel

- Declaration of interest
- Presenter
- Secondary presenter
- External referees
- Committee discussion
- Prioritisation
- Decision score

  - Finance available



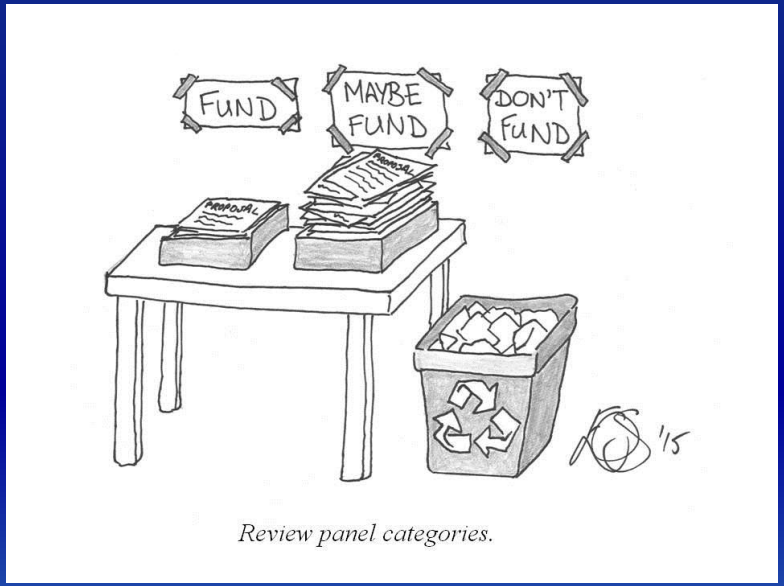
The research grant application process.

The Review Panel

- Applicant Track record, achievement
  Expertise
  Standing
  Ability
  Potential

- Environment Appropriate
  Commitment
  Opportunities
  Training

- Project Strength
  Innovation
  Methods
  Feasibility
  Value for money
  Impact



Review panel categories.

The Review Panel

- Resources
  - Essential
  - Value for money
- Ethics
  - Governance
  - Risk/benefit
- Data management
  - Security
  - Sharing
  - Access
- Impact
  - Human Health
  - Relieving disease
  - Pathway to impact
  - Involvement of patients/parents and target group

"Is it just me or are these review panels getting a lot tougher?"

HELP!

- Success rates

- Time involved – particularly in two stage proposals
  - Responding to referees
    - Maximising strength of the application

Our Project

- Aims
- Objectives
- Background
- Pilot data
  - Impact

Isaac Newton struggles to write the economic impact section of his 'gravity' proposal.

Our Project

The response to GH therapy in children with short stature born SGA is highly variable. We have preliminary data suggesting that in this heterogeneous group of patients, growth and IGF-1 response may be related to IGF-1 and insulin resistance at baseline. We plan to explore the hypothesis that insulin sensitisation through the addition of metformin could improve IGF-1 and growth response.

Aims

To determine the effect of insulin sensitisation on the response to Growth Hormone treatment in children born SGA.

Objectives

Primary Objective

To determine the effects of Metformin on changes in the circulating concentrations of IGF-1.

Secondary Objectives

1. To determine the effects of Metformin over one year on the growth velocity, insulin sensitivity, insulin secretion and glucose tolerance.
2. To determine the extent to which these changes in both Metformin and control groups are related to common variation in the genes which, in normal population are linked to insulin sensitivity/secretion, and in previous observational/pharmacological studies are linked to Metformin responsiveness.

Trial

Trial Design

Multicentre, double blind, randomised, placebo-controlled study

Trial Outcome Measures

- Primary outcome measure will be the differences in area under the curve of IGF-1 SDS across all post-treatment measurements.
- Secondary outcome measures will be the effect of the intervention on growth velocity, measures of glucose metabolism (insulin sensitivity, insulin secretion, disposition index and glucose tolerance), body composition and safety measures.

Eligibility Criteria

Inclusion criteria

- Small for gestational age
- Gestational age at birth > 28 weeks
- Short stature
- Age 4-9 years in girls and 4-10 years in boys
- Prepubertal at start of treatment
- Naïve to GH therapy

Exclusion criteria

- Known or suspected allergy to GH
- Previous participation in a GH trial
- Benign intracranial hypertension
- Diabetes
- Growth failure due to chronic diseases, syndromes, or chromosomal anomalies
- Psychological problems likely to lead to significant non-compliance
- Severe learning difficulties
- Previous or active malignancy

Plan of Investigation

- Design
- Primary
- Secondary endpoints
- Innovation

Trial

Investigational medicinal product and dosage

- Metformin 400 mg once daily

Active comparator product(s)

- None

NIMPs and challenge agents

- Growth Hormone

Route(s) of administration

- Oral

Maximum duration of treatment of a subject

- One year

Procedures

Screening and enrolment

The screening involves a clinic visit and will include evaluation of history, anthropometric data and pubertal assessment to check the eligibility of the patients.

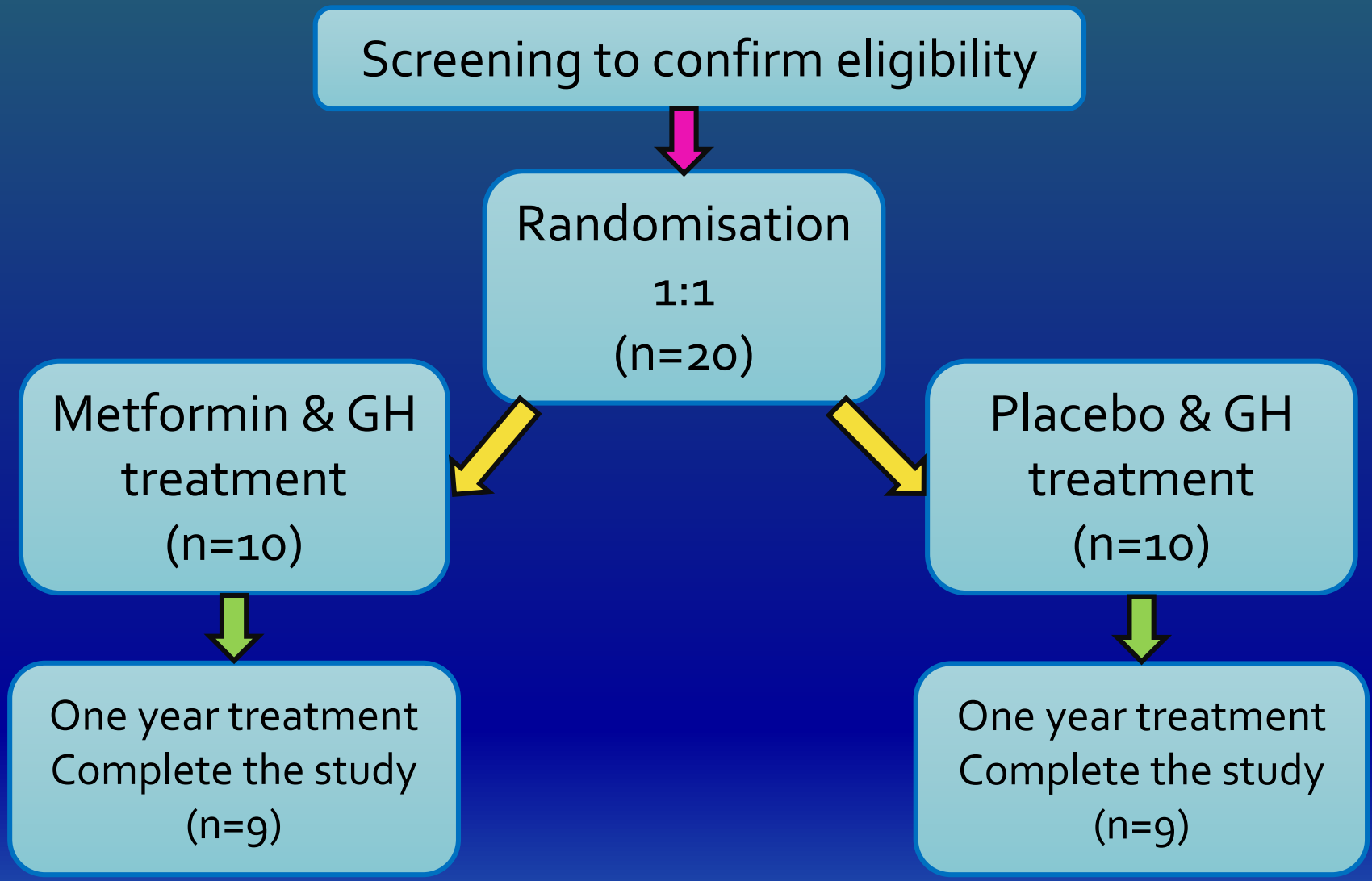
Baseline

The baseline visit will include measurement of anthropometry and skin folds, x-ray of the hand for bone age assessment, a DXA scan and an oral glucose tolerance test (OGTT).

Treatment period

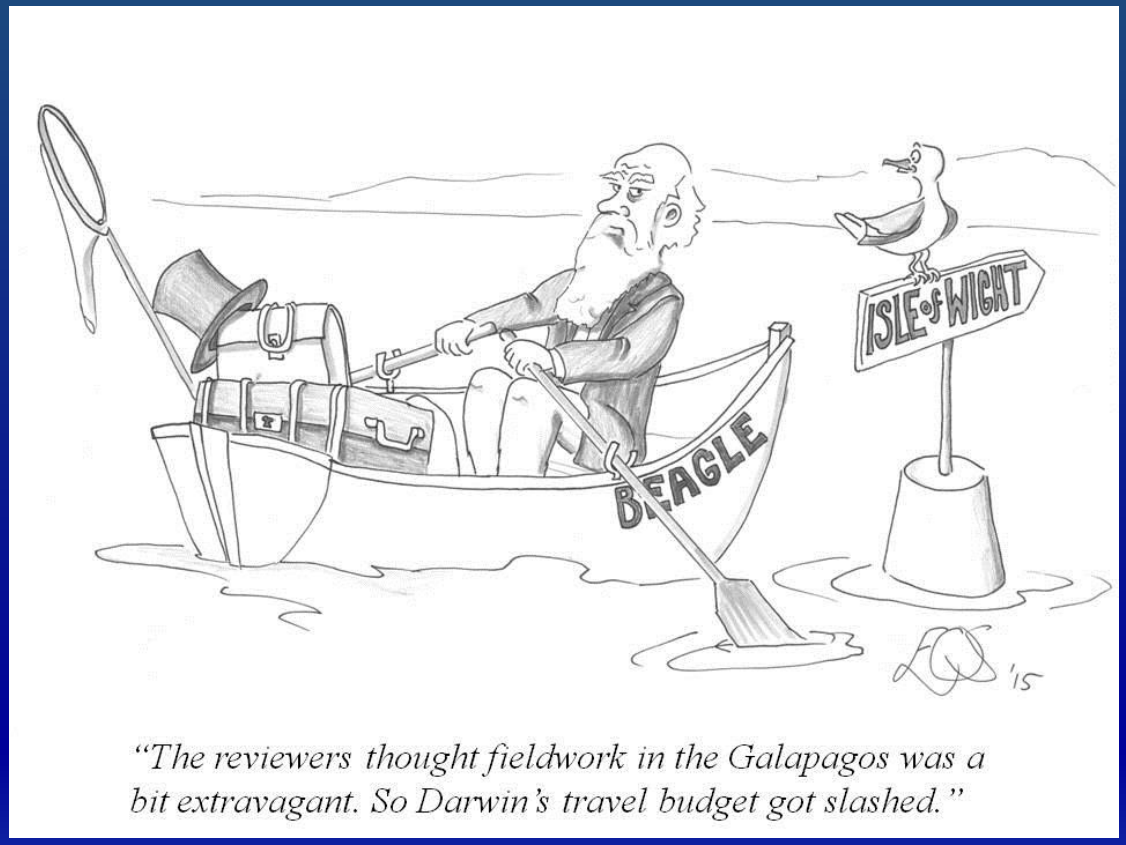
The patients will be seen at 1, 3, 6 and 9 months of starting the metformin treatment.

Trial Flow Chart



Research Costs

- Research costs
- Non research costs
- Institutional/health care support
- Value for money
- ? Sufficient



"The reviewers thought fieldwork in the Galapagos was a bit extravagant. So Darwin's travel budget got slashed."

Referees responses

- Is it feasible: do they have access to patients
- Have they engaged patient groups/public in their study development
- Insufficient pilot data

Feasibility

- Access to suitable patients
- Power calculations
- Experience of investigators
- Ethics
- Environment

Dr Frankenstein was disappointed with the letter from the Ethics Committee.

Applicants

- Balance, experience and support
- Record previous success
- Relation to publication record

Impact

- What is the impact, not only scientific but also target population
- Health service development
- IP
- Implementation

The research grant application process.

Your project

- A start up grant
- A grant based on your PhD or previous research productivity
- A grant in collaboration with a senior investigator
- A collaborative grant built through your work during your PhD or other research training
- Big science/collaborations

Multiple choice questions

1. Applicant suitability

    1. Where they trained?
    2. Who have they worked for?
    3. What is their expertise?
    4. How many grants do they have?

2. Why is the research question important.

1. The biology is interesting.
2. It will change clinical practice.
3. It could lead to further study of precision medicine.

4. It will lead to further basic research.

3. Power calculations are important.

1. Because they inform the effects size.
2. Because they indicate the size and feasibility of the study. 
3. Because they inform us of what the statistician suggests the sample size should be.
4. Because they will allow us to adjust the sample size to achieve clinical significance.

4. How will the committee prioritise the proposal.

1. Because of it's novelty.
2. Because of the success of the applicants.
3. Because the application has translational potential. 
4. Because the applicant has a very successful track record.


I ASKED SANTA FOR A RESEARCH GRANT.
YOU STILL BELIEVE IN RESEARCH GRANTS?
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