

STRATROC: Stratification Based Precision Treatment for Ovarian Cancer

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- MRC Outline Application to Stratified Medicine Expert panel approved for full application, full application 22nd June.
- Blood based diagnostic/prognostic biomarkers in ovarian cancer
- ctDNA (CNV, Methylation), metabonomics, Immunomics
- Assay and clinical validation, not discovery
- Stratification of surgical trials and maintenance therapies
- Links to Imaging trials (MROC, ROCKET)
- UK consortium (NCRI, SGCTG, **ECMC**)
- Work Stream Leads; Andrea Rockall, Sadaf Ghaem-Maghami, James Brenton, Ed Curry, Hector Keun, Kayleigh Davis, Jeremy Nicholson, Ros Glasspool, Iain McNeish
- PPI/PPE through Ovarian Cancer Action Voices
- Commercial Partners



STRATROC: Hypothesis and Vision

Earlier and more accurate diagnosis of EOC patients based on biomarkers in **pre-surgery blood samples and through treatment** will lead to more timely treatment choices and improved survival:

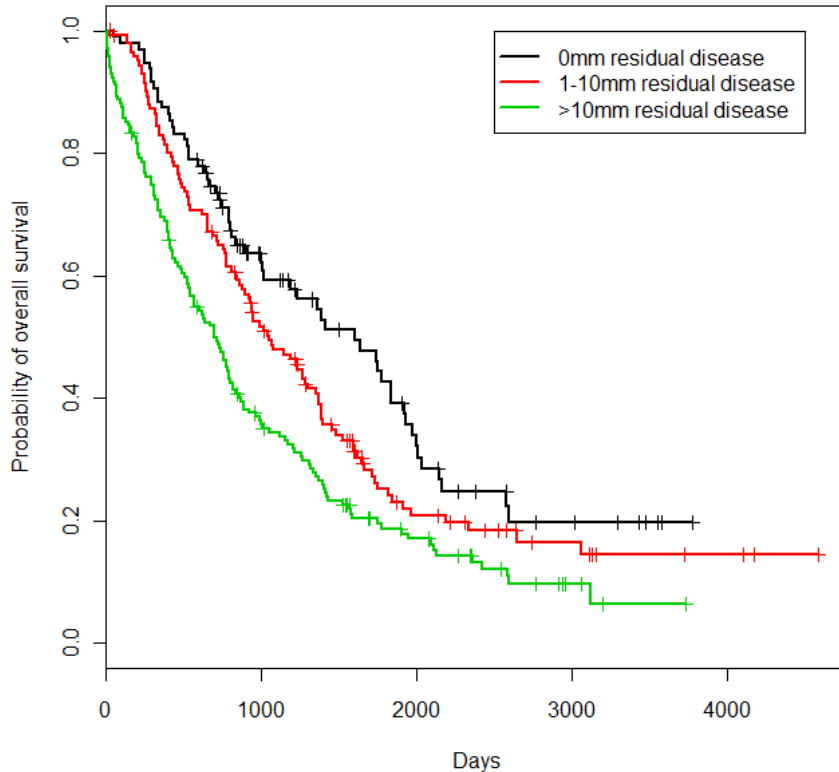
- less extensive surgery for those women with benign/borderline conditions and better planned surgery, as well as targeted treatments, for those with malignant disease.

The vision is to further validate function and mechanism related pathways into stratification biomarkers, together with cutting edge imaging, innovation in surgical technology and molecularly targeted/immunological therapies to deliver stratified clinical trials of EOC.

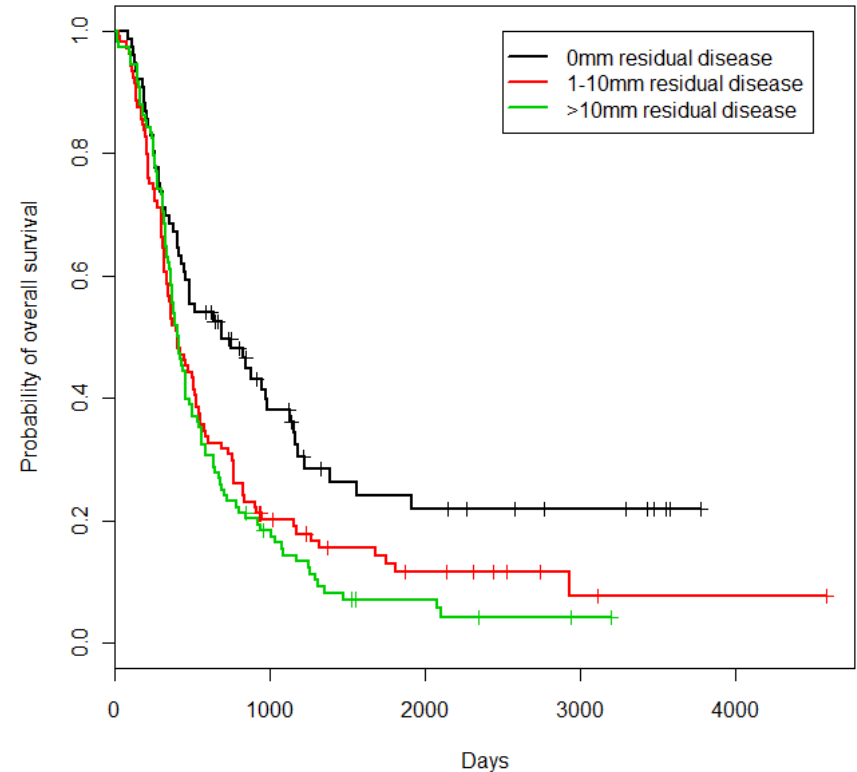


Surgery and survival

Overall survival $p=5.22e-05$,n=405

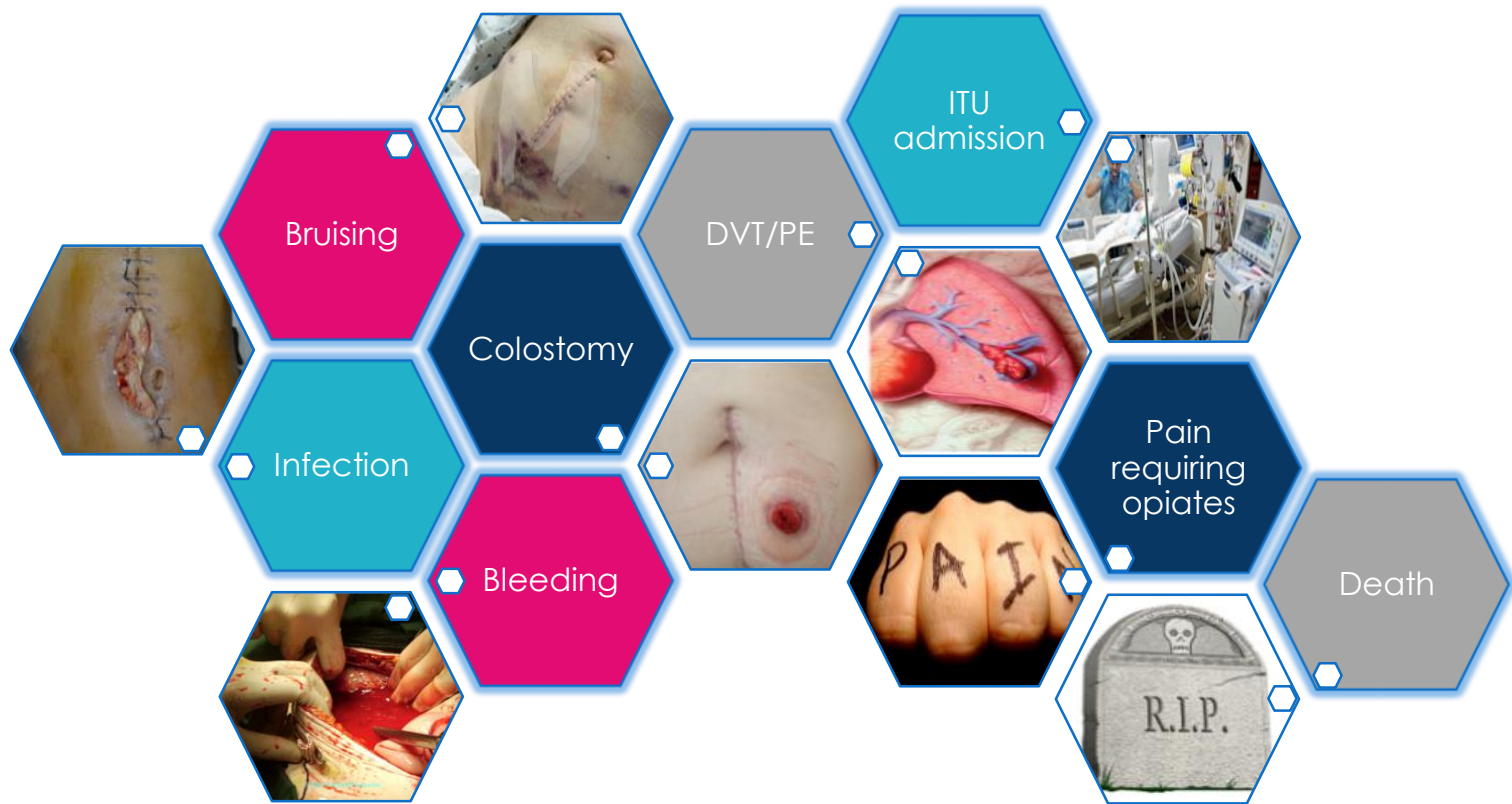


Progression free survival $p=0.00229$,n=288



450 patients from 2001 to 2010 with multiple data points collected. Age, stage, grade, histo, debulk status, organs removed at surgery, blood loss, OS, PFS, site of disease recurrence, nodal spread etc...

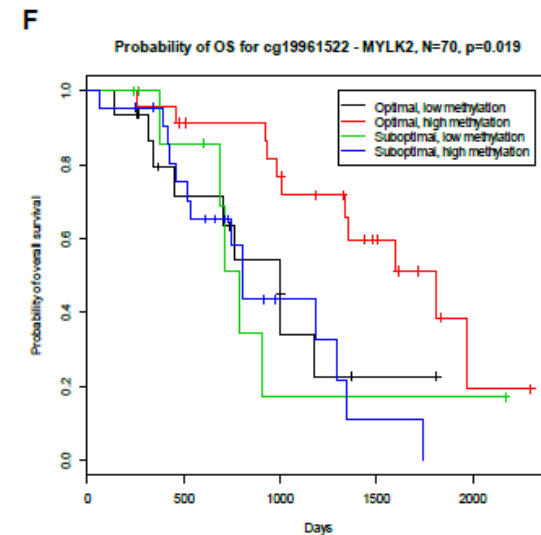
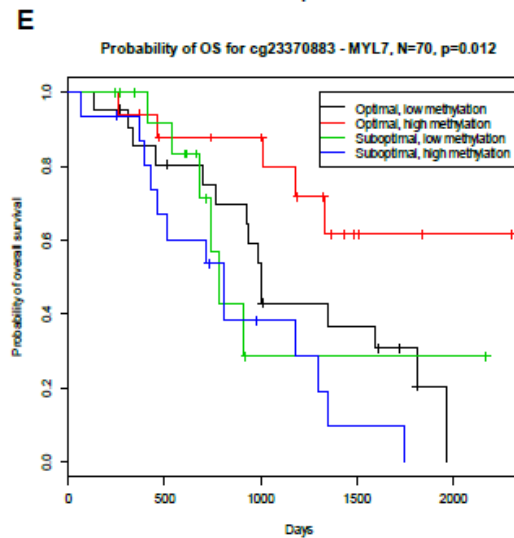
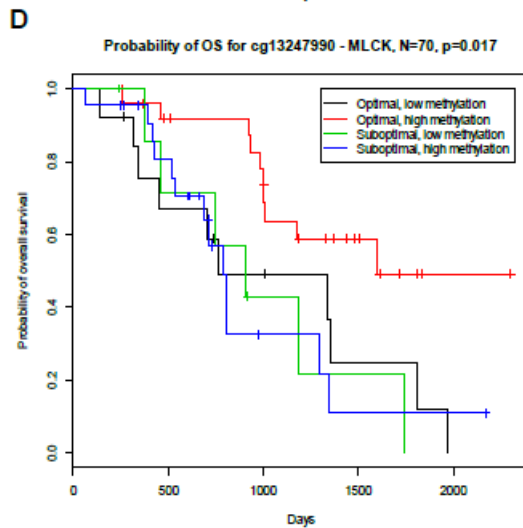
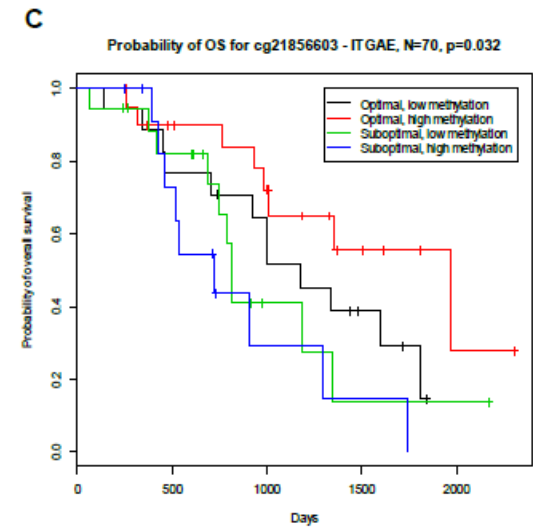
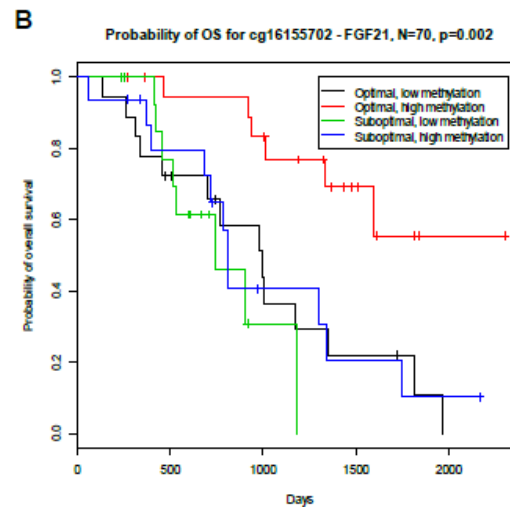
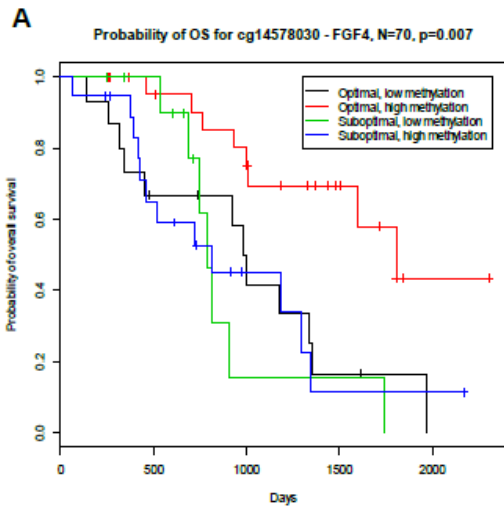
Complications from surgery



Surgery for ovarian cancer: Can we do better?

- Is the indeterminate ovarian mass malignant cancer?
- Should everyone with advanced ovarian cancer have a 'radical' operation?
 - Some patients have poor prognosis despite complete debulking
- When should we operate? Upfront or delayed?

Biology and Survival

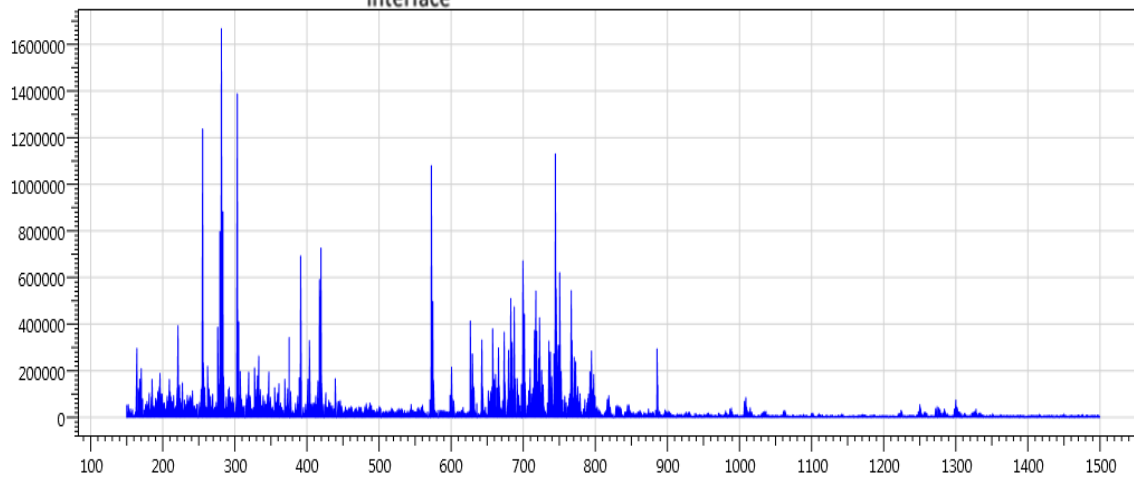
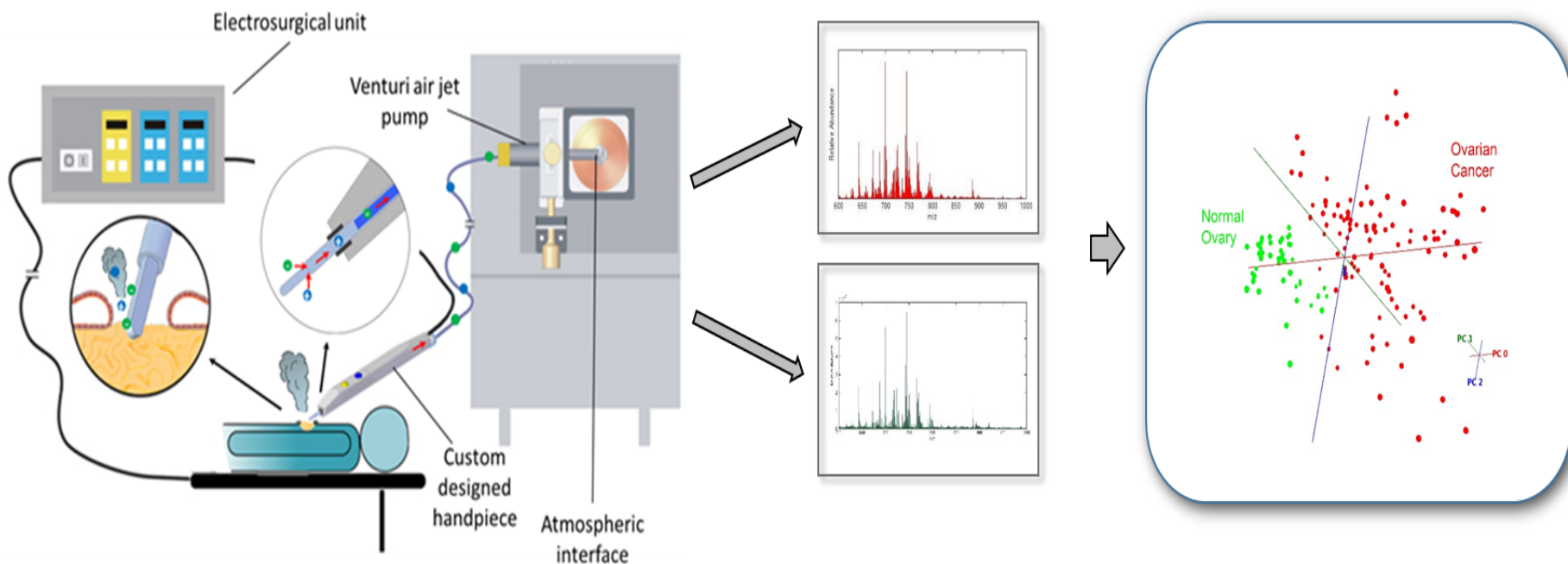


STRATROC: Outputs

- **Standardisation and validation of biomarker assays** with appropriate levels of quality assurance, focusing on CNV, DNA methylation, metabolic markers and immunological changes.
- Evaluation of biomarkers of **benign versus malignant** EOC in tissue biopsies and pre-surgery blood.
- Evaluation of **prognostic/predictive** EOC biomarkers in tumour and blood longitudinally through treatment.
- **Bio-statistical and systems oncology integration** of the optimal combination of biomarker and imaging for improved diagnosis and prognosis of patients.
- Biomarker/imaging driven stratification in **surgical clinical trials**.
- Biomarker/imaging driven stratified clinical trials of **novel therapies**, particularly in maintenance setting.
- **Sustainability** and translation into clinical delivery

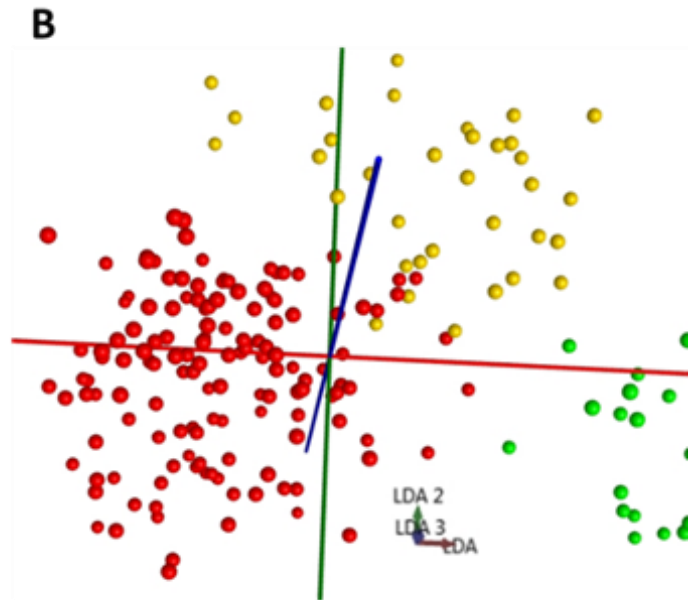
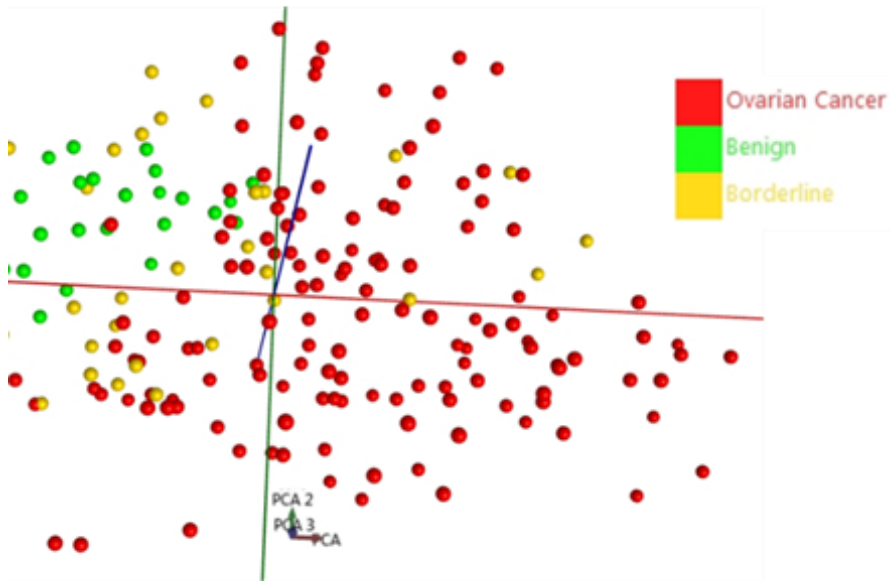


The iKnife: rapid evaporative ionisation mass spectrometry



Zoltan Takats
David Phelps
Sadaf Ghaem-Maghami

Benign/ Borderline/ cancer



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Overall correct classification		Predicted class		
		Benign	Borderline	Ovarian cancer
Actual class	Benign	93.3% (42)	6.6% (3)	0% (0)
	Borderline	0% (0)	97.8% (44)	2.2% (1)
	Ovarian cancer	1.0% (2)	5.6% (11)	93.3% (182)

What is the added value of having a commercial partner?

- intellectual value, which helps steer the study
- value of contribution in-kind, services and equipment which aid the consortium in delivery of its studies
- value in the purely financial sense, which increases the overall capabilities/capacity of the consortium
- Long term financial sustainability and clinical delivery

How did the collaboration with commercial partner start?

- Previous research collaboration with members of consortium
 - Testing of new assay or drug
 - Helping company validate their assay or equipment
 - Previous joint grant e.g. Innovate UK
- Personal contact
 - Clinicians with Pharma
 - Previous group members
 - Advisory Board
 - Networking
- Approach by the company
 - You are the inventor
 - You have the clinical samples or access to patients
 - You have the track record of delivery
 - Your data is robust

Company partnerships and collaboration

- Initiate discussion early and involve them in planning
- “In kind” may be more important than funding
- Define clear role for company
- Heads of Terms leading to Partnership Agreement
- Get the boring stuff done early: MTAs, CDAs, etc
- Identify key assay validation studies
- What does the commercial partner get?
- Define how the project will be sustained and become commercially viable at start of project

Identify Opportunities

- Joint grant e.g Innovate UK
- Internships and collaborative projects
- Road testing analysis and visualisation linked to clinical trials and NHS delivery.
- Being part of a national consortium
- Helping develop gold standard validated workflows for clinical analyses
- Brokering links with other companies e.g. biomarker to pharma