Clinical-Industry Partnerships
An Industry viewpoint

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Why should Academia partner with Industry?

Widespread deployment of innovation for the improvement of patient care

- Access to company base technology
  - Don’t reinvent the wheel!
  - Usually innovations are modifications of existing systems
- Industry can facilitate collaboration
  - Elekta’s MR Linac consortium
  - Varian’s FlashForward Consortium
Do you have something to offer a company?

- **Is your idea novel?**
  - Quite often ideas are not new
  - Do your research and be prepared to present the background

- **Is it valuable?**
  - How does your idea solve existing problems or create new opportunities?
  - Particularly, how can this idea be monetised?

- **Can it be protected?**
  - Often the value in an idea is patent protection if you have already publicised the idea you may have destroyed that possibility

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Technology landscape

- Ideally, your idea is going to be adjacent to the Advance development of the company
- This work is usually confidential but public clues can be obtained from patent applications

PS the size of the areas are not representative of the size of the activity or opportunity!
The ‘importancy gap’ and ‘time to market’

Super important
The company cannot wait for the approval of a grant funding body or the complexity of a collaboration. It will just fund this work from its own cash

Just important enough
This is the ‘sweet spot’ where neither of the other conditions apply. This is where collaboration can work.

Not important at all
The company cannot afford to invest the resources to support a grant application or a collaboration. Likely, nothing will happen

Which company is your best partner?

• Don’t assume that the company you know or work with is the best partner

• Is your idea in or adjacent to their scope of business?
  - It is very difficult and expensive for a company to change its scope

• Will it develop their products or their application?
  - For you to be able to answer this you need to understand their products and future roadmap
    - You need to do some desk based research
  - It has to be something that they are not already doing
    - You might need to enter into some deep discussions about their future
    - Possibly requiring an NDA – involve your legal department early

• Cultural fit …
How to approach the company

• Companies often do not like signing non-disclosure agreements
  - They may have already thought of your idea – this can lead to dispute and bad feelings
  - Try and file a provisional patent and then be prepared to make a non-confidential disclosure

• Develop your ‘pitch’
  - Why should the company find your idea interesting?
  - Why should they work with you?

• Companies will be looking for
  - Researchers with a demonstrated track record of innovation
  - Clearly thought out research project with deliverables

If you pass the initial ‘interview’

• If mutually interested then evaluate how to find funding
  - National and regional grants
    - You have the idea and make the application and we provide a letter of support
  - Direct Company Research Grant
    - If it is of sufficient interest then the company might want to retain control
    - Might provide early access to new product features
    - Access to restricted research interfaces

• Examples of Academic/Industrial projects with external funding
  - CBCT, Portal Dosimetry and MR Linac (proof of concept)
Why might a company not favor a grant application?

- **For**
  - Funding support, but often this primarily goes to the researcher
  - Ability to investigate something that might not be investigated otherwise
  - Access to data can be a motive for a company

- **Against**
  - Time and investment required for application with the possibility of rejection - waste
  - Administration overhead during project
  - Lack of control over timeline
  - Possible loss of IP
  - Lack of flexibility/long term commitment

Current AIP Example: MDACC and Elekta

- **Aim**
  - Development of functional MRI adaptive therapy for Head & Neck Cancer patients using MR Linac
    - Develop requirements, implement prototype and test in the clinic

- **Funding**
  - NIH (PAR-18-009), Academic-Industrial Partnerships to Translate and Validate in vivo Cancer Imaging Systems (R01)

- **Contributions**
  - MDACC: Clinical research and validation
  - Elekta: Auto-segmentation and plan adaptation using functional imaging
  - Philips: DWI optimisation

PI: CD Fuller, MD Anderson
How to help your company advocate

• Critical to success of the project is the ‘buy in’ of the company management
  - They need to believe that this is ‘important enough’
  - We want to try and avoid the company changing its priorities during the project
• You will likely be in contact with a research manager and they will need your help to get this ‘buy in’
  - Listen to their challenges and help find solutions
• Do not view this as a burden but as an essential component of the process

Compliance and Integrity

AdvaMed Code of Ethics and the Anti-Kickback Statute

• Neither party should use research as a means to achieve improper gain
  - Especially to influence a commercial transaction and especially in the USA
  - Needs to be clear and evident value for money (“Fair Market Value”, FMV)
• Companies must use their shareholders’ money in their best interest
• Research plan with clear milestones
  - Can be amended with mutual agreement
• Progress reports*
  - Demonstrate that appropriate work has been done for the payment

* Well written progress reports are also an opportunity for you to help the company research staff promote you and your work within the company – help them to help you!
Some lessons learned

• Develop the plan together
  - Start with a joint brainstorming meeting
  - The application should document the mutually agreed approach not just be 'your plan'

• Important to agree on expectations
  - If you need some deliverable from the company be explicit
  - Do not assume that you will get something that is not spelled out
  - Company resources are usually under a lot of pressure with other priorities

• The application should play to each others’ strengths
  - The deliverables should be in the core of each party’s daily activity
  - E.g. clinical applications vs technology

More lessons learned

• Avoid making assumptions about continuing support
  - Just because you got company support for one application do not assume that if you fail and re-apply that this support still exists

• Company priorities change
  - Within the scope of the project it might be that the company’s commitment to the project changes over time
  - This is likely to be nothing to do with you or the project, there are many other pressures on companies
What makes the relationship work?

- **Mutual Respect**
  - Recognising each others priorities, needs and constraints

- **Open Communication**
  - Good news and bad

- **Patience**
  - Even good ideas are initially met with scepticism
  - Bringing a product to market is very complex and takes much longer than you would think

- **Realistic**
  - There are times when things don’t work out and it is nobody’s fault
  - If you are too demanding financially or otherwise the company will probably find it cost effective to find another way to do this work

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A changing research landscape

- **Collaboration used to be all about technology**

- **Balance is shifting towards clinical research**
  - Increasing emphasis on demonstrating the clinical value of innovation
  - Especially if cost is increased

- **Example of MR Linac – Elekta Unity**
  - **MOMENTUM** *
    - Prospective international registry
    - Reported on early toxicity of 1800 patients at ESTRO
  - Hypothesis Testing Program

* [https://www.lygature.org/momentum](https://www.lygature.org/momentum)
How do we want this to end?

• Learning
  - Whatever else we achieve, we hope that we will both learn something valuable going forward

• Still ‘friends’
  - It is totally undesirable for the outcome of an AIP to be a broken relationship
  - However, it is so easy for this to be the case

• An upside is a commercial outcome
  - Some new feature or product which allows the community and patient to gain from the collaboration

Thank you