

# Clinical-Industry Partnerships

## An Industry viewpoint

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## Why should Academia partner with Industry?

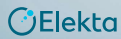
**Widespread deployment of innovation for the improvement of patient care**

- **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

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## 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

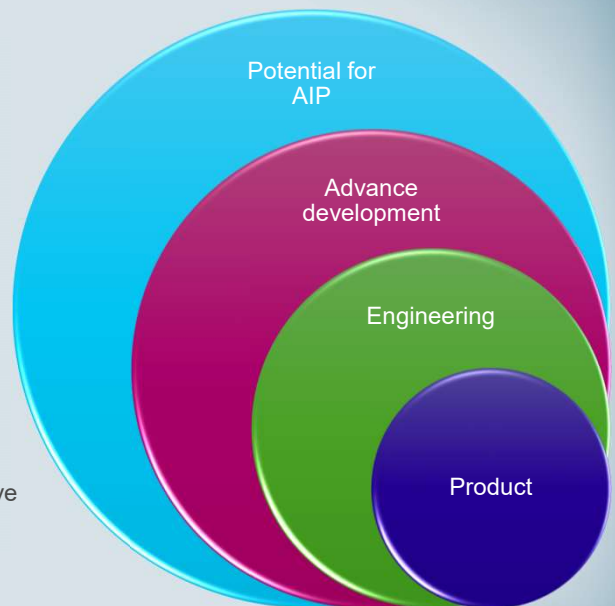


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## Technology landscape

- **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!



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## The 'importance 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

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## 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 ...**

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## 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



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## 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)



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## 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



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## 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

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## 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**



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## 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!*



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## 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

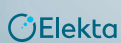


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## More lessons learned

- **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



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## 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

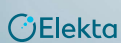


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## A changing research landscape

- **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>

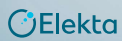
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## How do we want this to end?

- **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



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**Thank you**

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