

Reaping the benefits of an integrated approach to clinical research

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Clinical Research Excellence Q&A

An integrated approach to clinical research

My task today.....

Looking at how the greater research community is collaborating and exploring areas where there is:

- lack of consistency
- emergence of new models of collaboration



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- My credentials
 - Clinician
 - Researcher
 - Industry links
 - Clinical trials
 - Scientific and Clinical Advisory Boards
 - Government and NGO Research Advisory Boards
 - Start-up Biotech Company



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Advantages

- Strength of collaboration
 - Whole greater than sum of parts
- Overcome low population (density)
 - International competitiveness
- Avoid duplication
- Avoid multiple “learning curves”
- Create efficiencies
 - Finance, contracts, ethics, completion time



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Disadvantages

- Dilution of kudos
- Reduced individual revenue
 - Total funding less than the sum of parts
- Lack of identified point of contact
 - Leadership, responsibility, communication
- Individual groups lose opportunity to grow or innovate
 - Henry Ford, research activity resembles “service”



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Existing opportunities

- CCRE
- NHMRC Program grants
- NGO initiatives
- Multicentre trials
- Institutes
- “Consortia”



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Existing difficulties

- NHMRC Program grants
 - Reduced opportunity for new areas of research
- NGO initiatives
 - Disease-specific
- Multicentre trials
 - Difficult to involve true exploratory research
- Institutes
 - Rarely have substantial research funds
- “Consortia”



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Barriers – “systemic”

- Communication
 - Personal, IT
- Infrastructure
 - Space, equipment,
- Lack of expertise
 - statistics, legal, contractual, commercial
- Ethics, Contracts, IP
- Geography



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Barriers – “Individual”

- Time
 - Staff specialist – 0.7 clinical load.....
 - Hierarchy for use of available time
 1. Own research
 2. Local collaboration
 3. Distant collaboration
 4. Collaboration with other disciplines
- Dilution of reward
 - Research income
 - Authorship
 - Leadership opportunities



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Barriers – “Individual” (continued)

- Grief
 - Contracts
 - Ethics
 - IP – little reward in many systems
 - Communication
 - Invasion of “protected time”
 - Conflict with clinical commitments
 - Time management



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Commercial backing

- No cream
- Very tight externally-applied timelines
- Rigorous reporting demands
- IP diluted or taken
- Externally-driven agenda and aims
- Opportunity to “add on” own research questions
- Minimal/no flexibility



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Non-commercial backing

- No cream (and not much milk...)
- Few externally-applied timelines
- Very reasonable reporting demands
- IP yours
- Investigator-driven agenda and aims
- Opportunity to “add on” own research questions
- Flexibility ++



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Ways forward

- Give more research time on a competitive basis (happening inconsistently)
- Sort IP issues, with national consistency
- Get more of the limited cream to the researchers – this is how to fund innovation
- Consider a “performance pot”
 - Profit margin
 - Grant extension
 - Clinical backfill



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Ways forward

- Researchers need to divide their activities into “service” research and investigator-driven research
- More contract research
 - Cost recovery for own work
 - “Mates rates” for collaborators
 - Commercial rates
- Sort communication etc
- Collaboratively engage industry



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Conclusions

- Collaborative research –
 - Rewarding
 - Efficiency gains
 - Geography is a barrier for clinical research
 - Requirement to consider some aspects of research as a revenue source
 - Opportunities lost and gained for acquiring skills
 - Inadequately funded
 - Need to engage business-type administrative structure



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