SUCCESSFUL CLINICAL DEVELOPMENT - IMPROVING THE ODDS

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OVERVIEW

- Clinical development - setting the scene
- What are the odds?
- Improving the odds - key considerations
- Australia

CLINICAL DEVELOPMENT IS….

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A set of experiments in patients or human volunteers to establish if a new therapy is safe and effective and is…

- Complex (capability)
- Competitive
- Highly regulated
- Very time consuming (average 5 yrs -range 2-10)[1]
- Resource intensive
- Expensive (capital)
- Company maker / breaker
- Risky - low success rates…

[1] Source – Dickson & Gagnon, 2009

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PROBABILITY OF REGULATORY APPROVAL BY CLINICAL PHASE

Phase I: 9%

Phase II: 15%

Phase III: 44%

Submission: 80%

Risk varies across therapeutic areas /indications

Source - BIO CEO & Investor Conference - February 15th, 2011

SUCCESSFUL CLINICAL DEVELOPMENT

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- Defined strategy / specifications
- Risk managed
- Commercially relevant
- Clinically relevant
- Outsourcing - appropriate partners
- Protocol - practical
- Time – realistic estimates
- Strong & productive relationships

- Compliant
- Clinical outcome for commercial success: partnering/sales

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1. WHERE DO YOU WANT TO GO?

"Would you tell me, please, which way I ought to go from here?"
"That depends a good deal on where you want to get to." said the Cat.
"I don't care much where ---"
said Alice.
"Then it doesn't matter which way you go" said the Cat.

Lewis Carroll

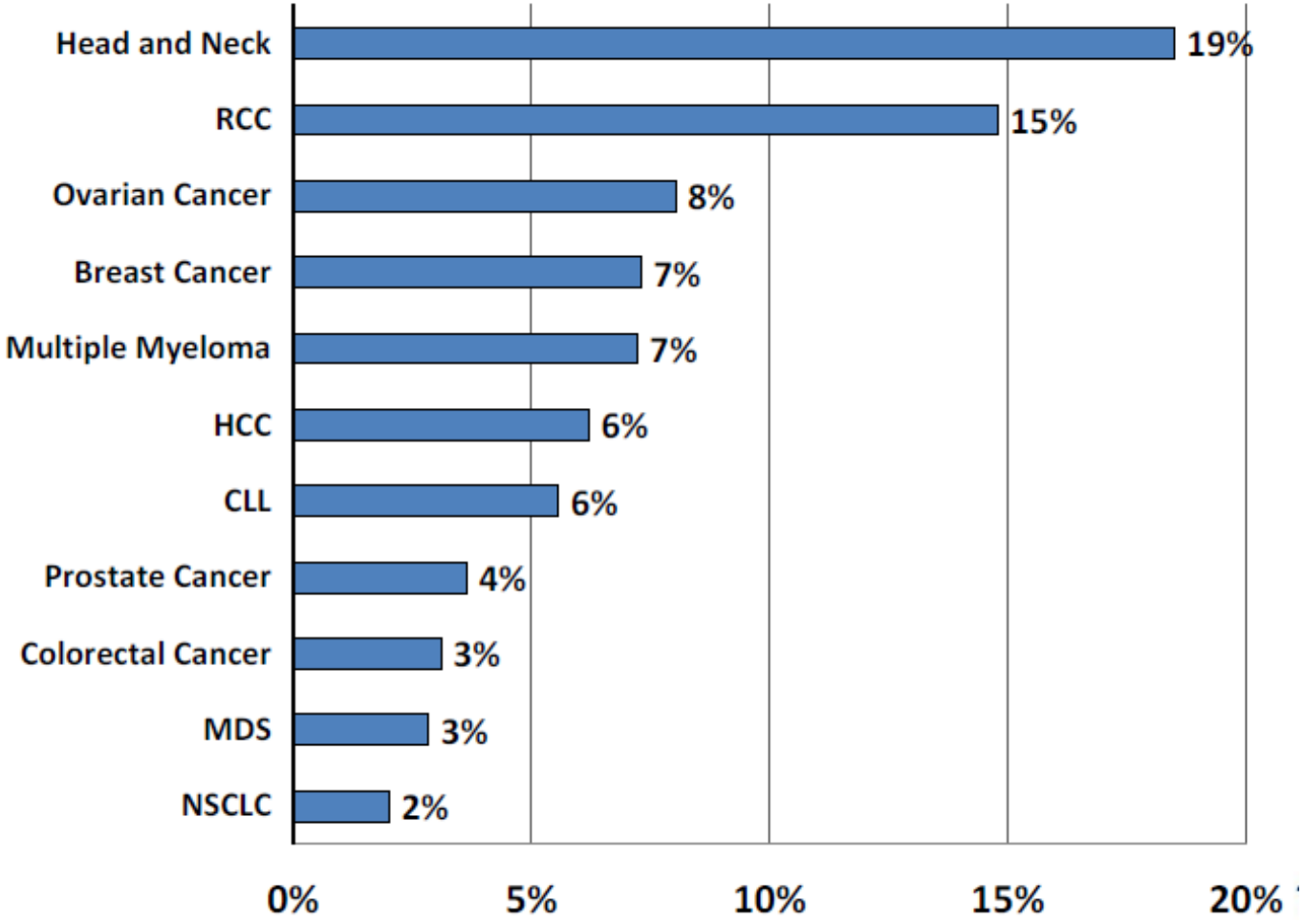
2. DEFINING THE PRODUCT - EARLY INPUT

- An antibody treatment for melanoma or….

- A mAb treatment for melanoma which has safety and efficacy advantages compared to BRAF inhibitors and can be used as monotherapy or combination or for BRAF resistance
- Efficacy advantages in 2 different pre-clinical models compared to BRAF
- Human half life to allow fortnightly (min weekly dosing)
- Manufactured to yield of at least 2gm / litre
- Target dose of < 100mg

- Review, revise and expand as development progresses

OVERALL SUCCESS RATES - ONCOLOGY



Source - BIO CEO & Investor Conference - February 15th, 2011

3. THE NEED FOR RISK MANAGEMENT FULLER'S LAW…

4. GET CAPABLE- SELECTING EXPERTISE

- Good (cultural) fit to your organisation?
- Risk sharing options?
- Appropriate therapeutic vs operational experience?
- Timely financial reporting?
- Location
  - Key people in your country / time zone?
  - Experienced operational staff where you need them ?
- Financial stability?
- Personnel continuity? (critical functions)

5. PROTOCOL

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- Appropriately powered for aim
  - is a 10% decrease clinically relevant?
- Regulatory & clinically appropriate endpoints (validated)
- Comparative agent (available & used in selected country)
- Realistic inclusion/exclusion criteria → allow patients to be found
- Don't overburden assessments / visits → allow patients to consent
  - Use "grandmother" test
- Complexity - can protocol be conducted in target setting?
- Allow flexibility: e.g. visit 7 days +/- 2 days
- Reality check – what happens if "X" doesn't happen / is late etc ?

6. TIME

- Anticipate and allow for (inevitable) delays
  - Ethics, recruitment, vacation, funding…
  - Important for public statements / ASX
- Use realistic (not optimistic)
  - Recruitment estimates
  - Feasibility assessments using protocol
  - Pperational timelines e.g. protocol review and approval, DBL
- Consider back-up sites / countries
  - Rule of thirds: 1/3 do well, 1/3 do something, 1/3 do nothing !!
  - Impact of vacation season (use Nth and Sth hemisphere)

7. RELATIONSHIPS

- Develop good relationships with study team
  - Investigators
  - CRAs
  - Study coordinators
  - Vendors

- You are competing with +++ other studies, distractions

- Is there back-up for key team members?

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CLINICAL DEVELOPMENT IN AUSTRALIA

- The ideal first in man / POC destination
- Favourable regulatory climate
  - Clinical Trial Notification (CTN) Scheme
  - Approval delegated to Ethics Committees
  - Documentation ”lite” = protocol + IDB
  - No IND required – can commence pre-IND
- State of Art Phase I units
  - Highly trained & experienced Investigators
- Generally fast start times

THANKYOU

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