



Why do we do Clinical Trials?

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Introduction

- What are clinical trials?
- Brief history of clinical trials
- Who benefits from clinical trials
- Medical Oncology Clinical Trials

What are Clinical Trials?

“Clinical Trials provide the evidence basis for rational decision making in medical therapeutics”



A Coates AM

CEO, The Cancer Council Australia

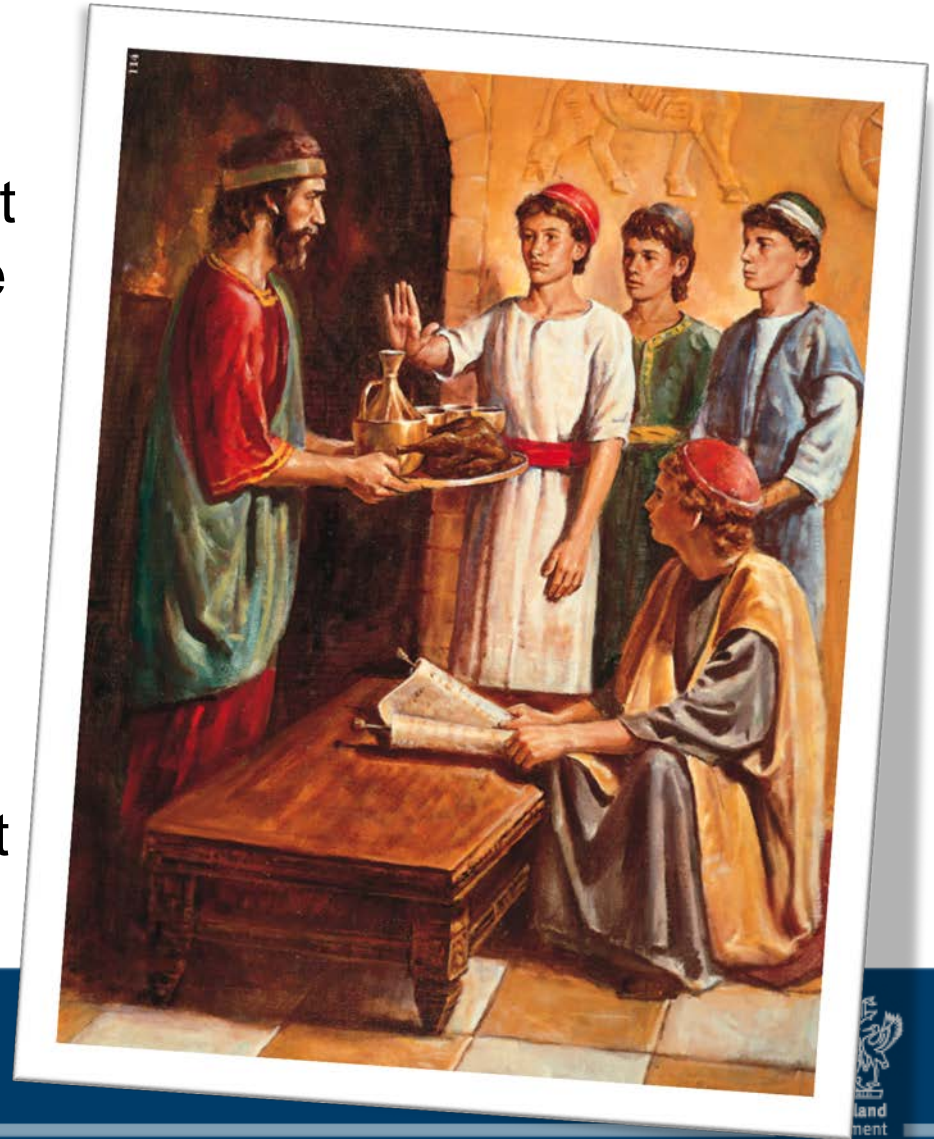
International Breast Cancer Study Group

Australian New Zealand Breast Cancer Trials Group

Sydney, NSW

Where did it all Begin?

- The earliest record around **530-540 BC.**
- King ordered his people to eat only meat and drink only wine
- Daniel and his followers preferred vegetables and water.
- King allowed the rebels to follow their diet for 10 days.
- Vegetarians appeared in better condition than the meat and wine imbibers



Lind Scurvy Trial

- **1747** James Lind was the first to introduce a control group to a clinical trial.
- Documented that citrus fruit in the diet could prevent scurvy
- Nearly 50 years before the Navy made citrus a compulsory part of the seafarer's diet.



Modern Trials are Complex





Clinical Trials Beneficiaries

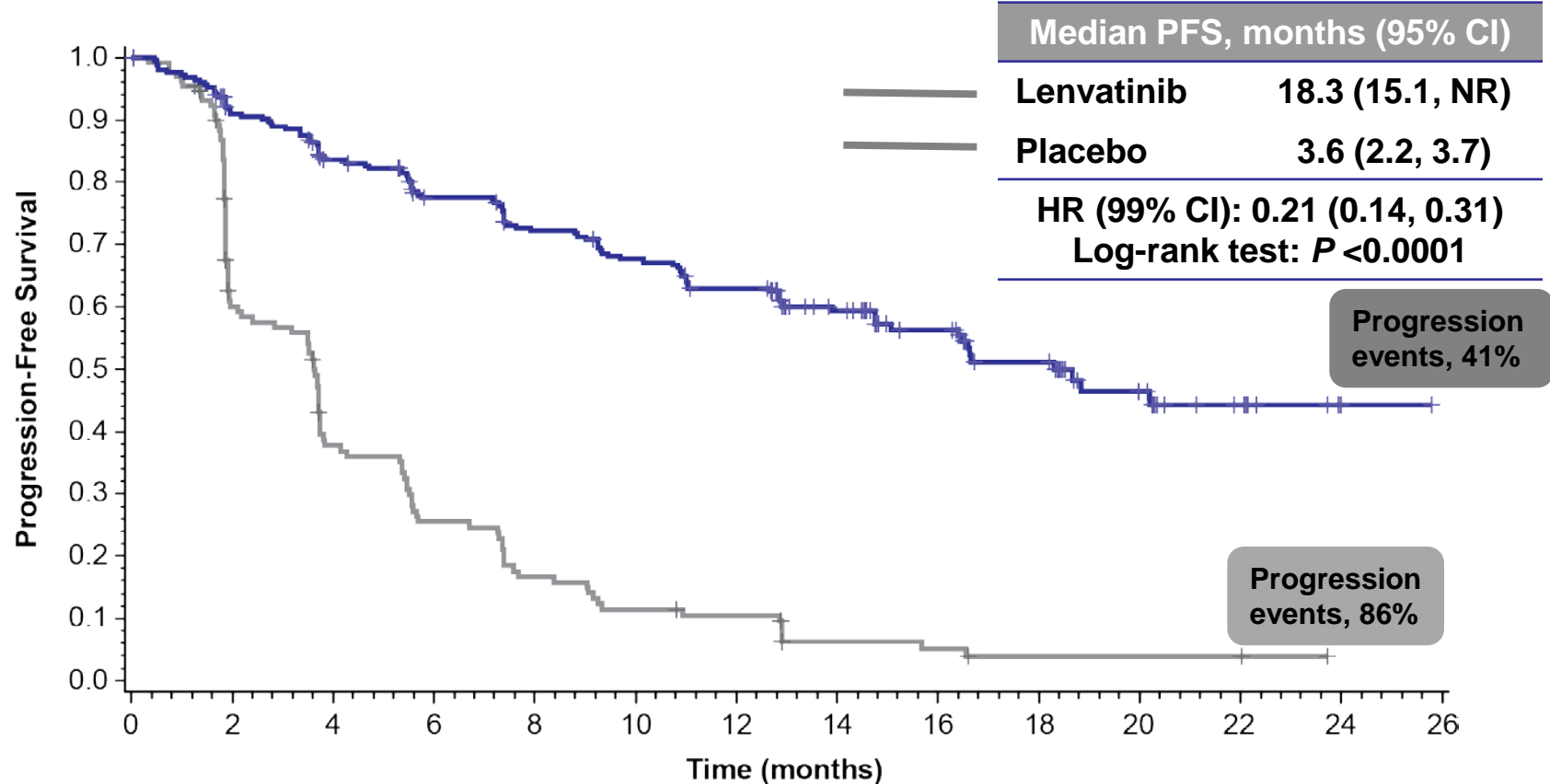
1. Participating patients
2. Future patients
3. The community
4. Health Care Professionals
5. Third party payers (e.g. government)



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Primary Endpoint: PFS



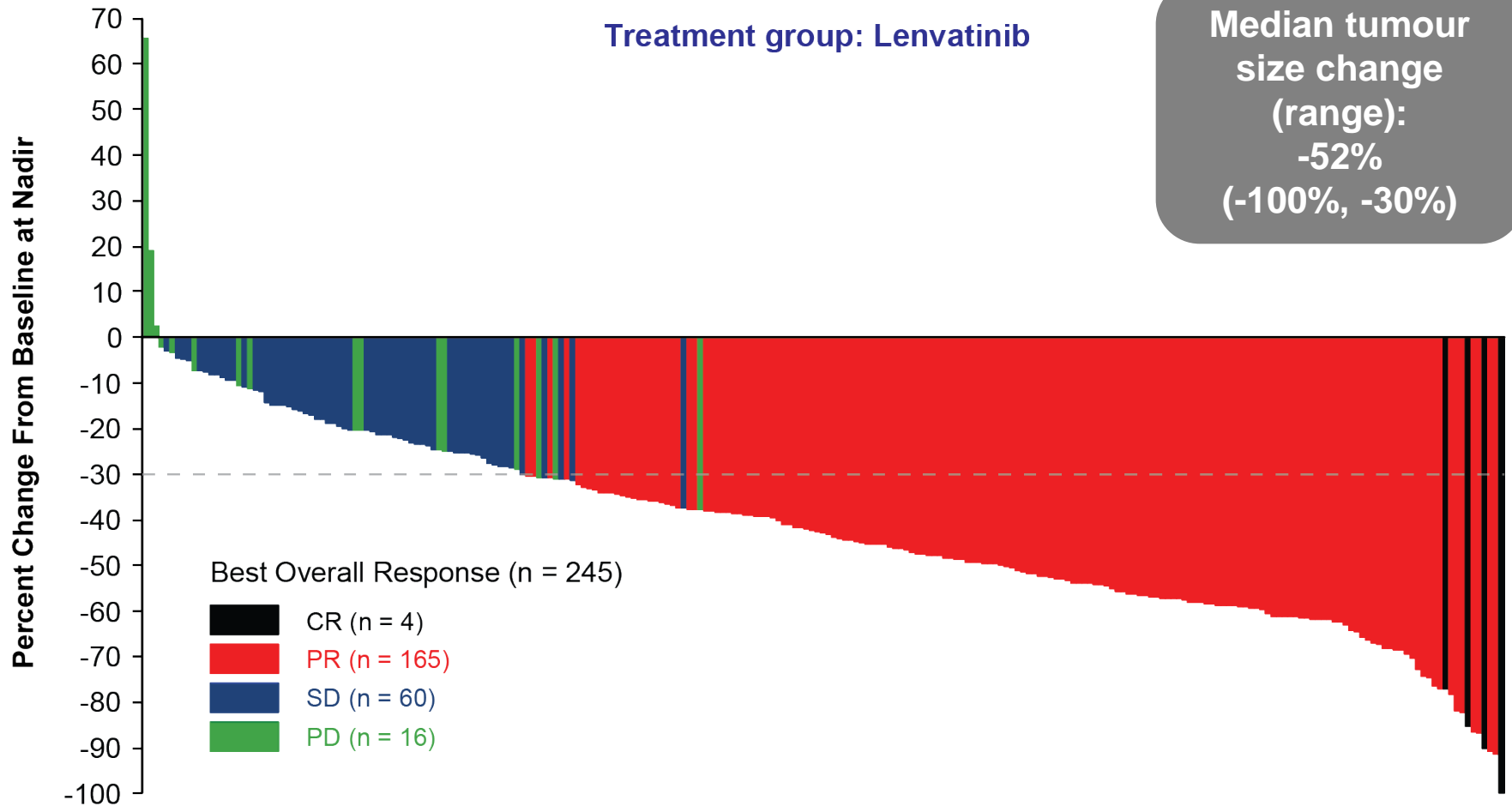
Number of subjects at risk:

Lenvatinib	261	225	198	176	159	148	136	92	66	44	24	11	3	0
Placebo	131	71	43	29	19	13	11	5	4	2	2	2	0	0

Magnitude of response: Lenvatinib

Treatment group: Lenvatinib

Median tumour
size change
(range):
-52%
(-100%, -30%)



CR, complete response; PD, progressive disease;
PR, partial response; SD, stable disease.



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Future Patients





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The Community



“Human clinical trials start in six months.
Sooner if we run out of mice.”



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Health Care Professionals





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Third Party Payers





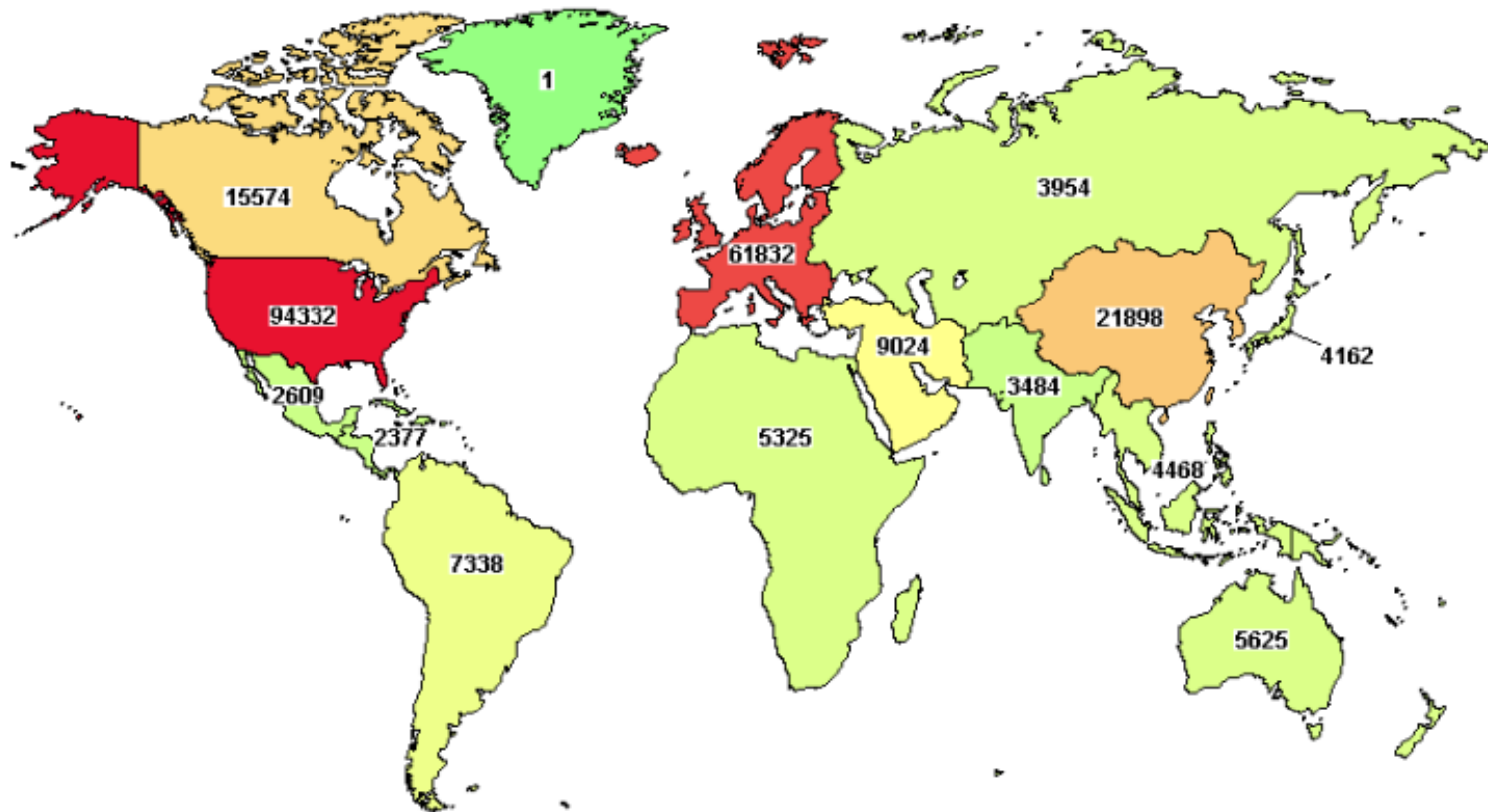
Clinical trials are good value for money

**“Combined health and health system
returns in the order of \$3 to \$5, *per year*,
for every dollar of one-off investment”**

ACTA June 2016

(submission to MRFF Advisory Board)

International

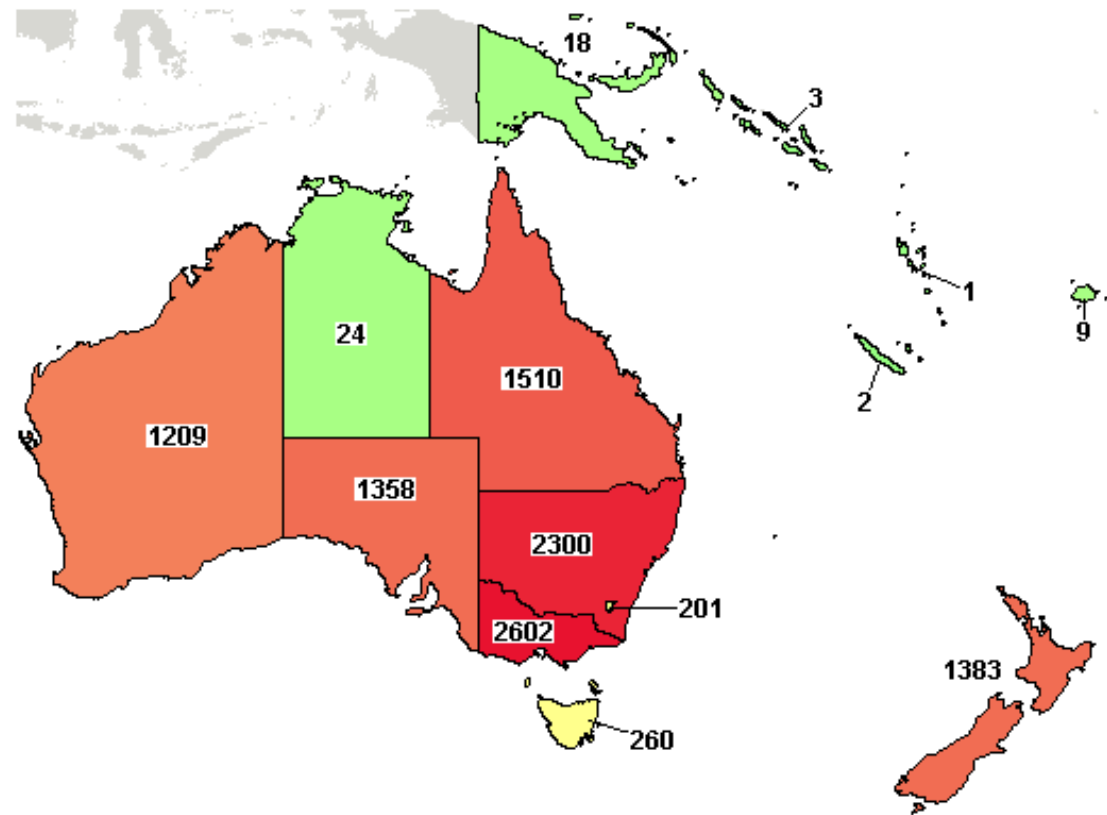


Colors indicate the number of studies with locations in that region

Least  Most

Labels give the exact number of studies

Australia



Colors indicate the number of studies with locations in that region

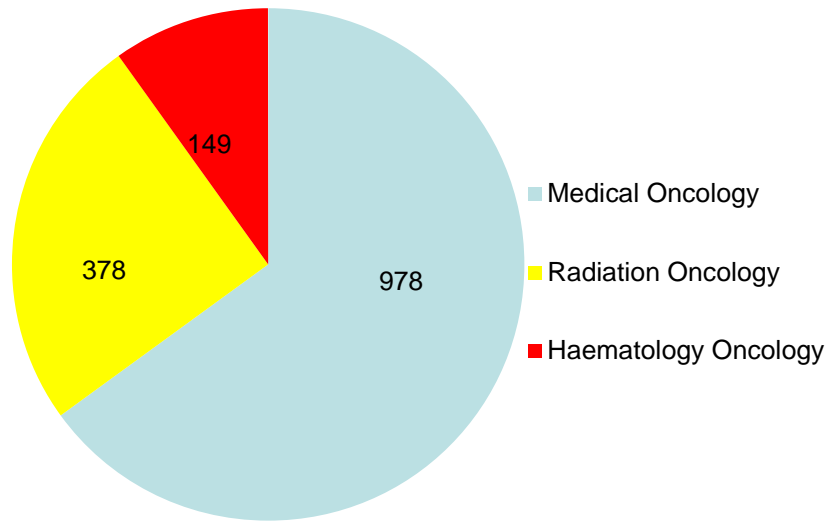
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Labels give the exact number of studies

Cancer Care Services Clinical Research Unit

July 2016

Patient Recruitment Numbers



- 1505 Total Number of Patients



Medical Oncology Clinical Trials

- Started 1995
- 11 Oncologists
- 11 FTE research staff
- 10 broad tumour groups
- 90 active studies, 30 recruiting.
- Nearly 1000 patients on a clinical trial.
- Started 8 new studies this year, 13 on the books to start in the next few months.
- The number of studies offered has ramped up
- Hold on new studies due to insufficient resources. Includes staff and space.



“You see, if we want a great health care system, yes we need hospitals and equipment, but to provide for an ever improving health system - we need research.”

Professor Johnathon Morris AM,
Chief Investigator ACTA Clinical Trial of the Year 2016



**Australian
Clinical
Trials
Alliance**

Our Staff



Our Patients

They are not -
**“Subjects in a Clinical
Trial”**

They are -
“Partners in Research”

(Dennis Slamon)

