

Early Phase Trials in New Zealand

Chris Wynne

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Conclusion

- Physician led
- Flexibility and adaptability
- Proven ability to recruit for patient studies
- Complex analytical and imaging capabilities
- Robust favorable Ethics /Regulatory Environment
- Cost-effective Quality Research

Phase I & II trials

**New
chemical
entity**



pre-clinical



clinical



marketing

I  **II/III**

Timeline

0



10-14 Years

**Number of
compounds**

1000



100



10

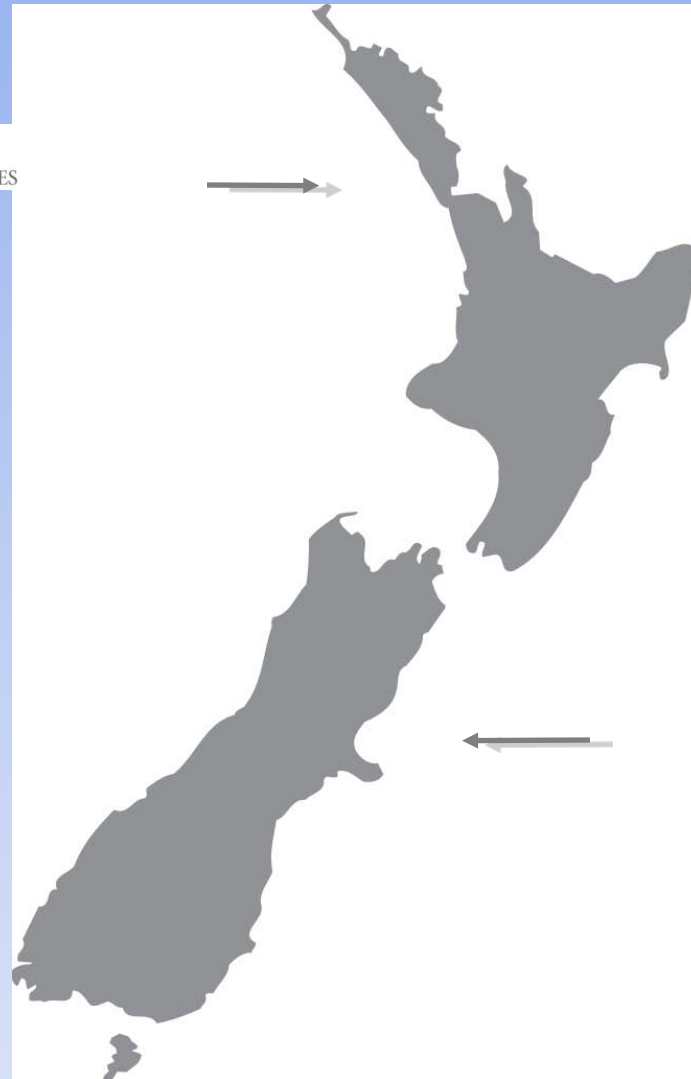


2-3

Introduction

- Types of studies
 - Phase 1
 - Phase 1b-2a
 - PD/PK disease states
 - Unregistered drugs, non-oncology studies
- Sites
 - CCST
 - ACS
 - Primorus

ACS | AUCKLAND
CLINICAL STUDIES



CCST Christchurch Clinical
Studies Trust

Facilities

- Two Clinical Pharmacology units
- Co-located with teaching hospitals
- 40 beds
- 45 FTE staff
- Pharmacies
- Laboratories



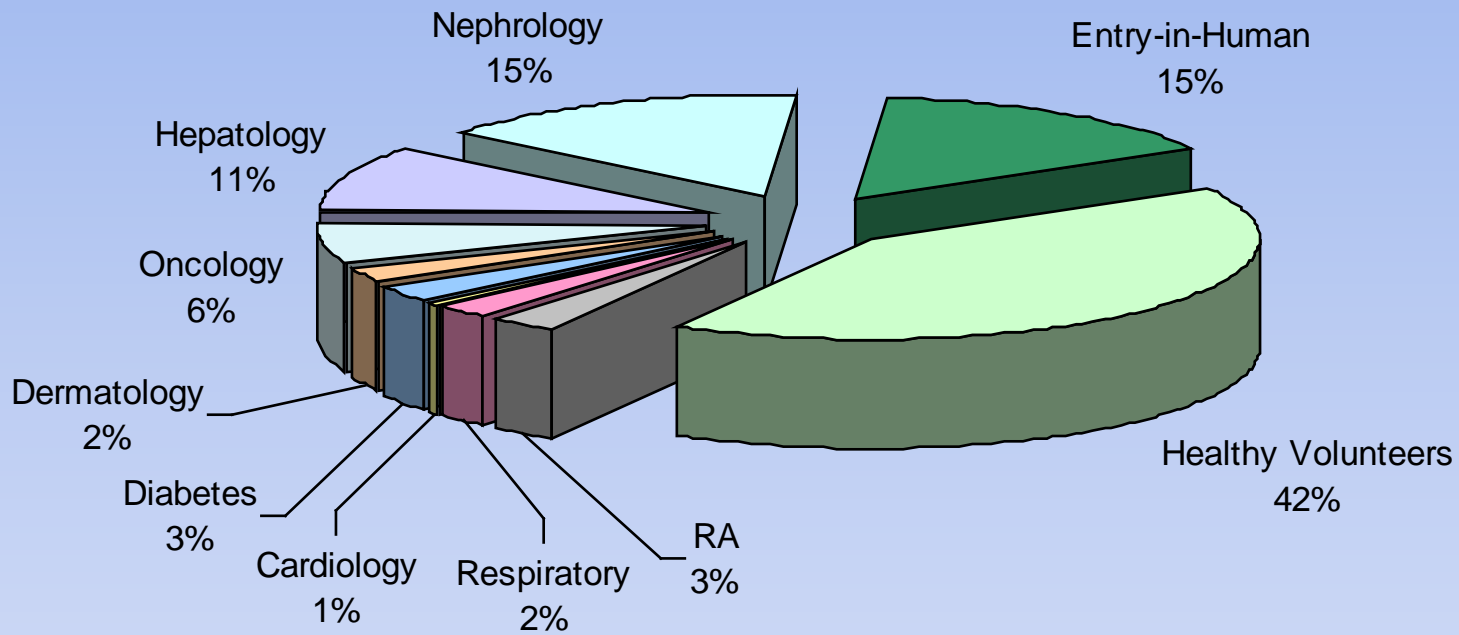
Type of Studies

- Entry-in-Human
 - Small & large molecule
- Umbrella protocols (SAD/MAD/FE/Patient)
- Special Populations
 - Renal Impairment
 - Hepatic Impairment
 - Asian
- Drug/drug interaction
- ADME
- Bioavailability
- Food Effect
- Proof Of Concept
- Mass Balance

Patient Groups

- Anaemia
 - Renal patients
- Allergic rhinitis
- Antibiotics
- Depression
- Hepatitis C
- Influenza
- Parkinsons
- Osteoporosis
- Multiple sclerosis
- Oral contraceptive
- Pain
- Immunosuppression
- Urinary incontinence

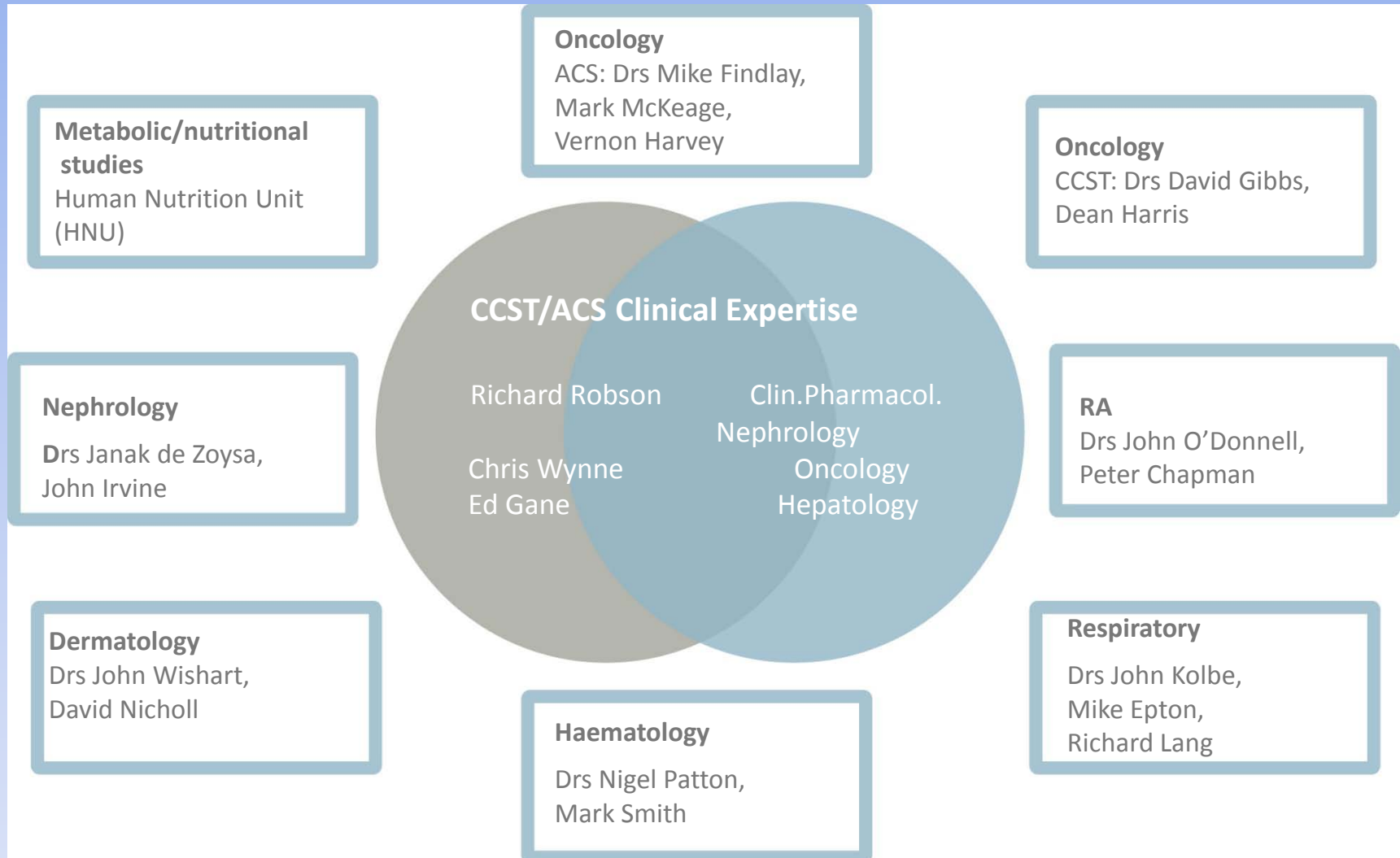
Studies Across Therapeutic Areas



Total Phase I/II studies

140

Clinical Expertise



Lab Capabilities

- **CHL & LabPLUS - reference labs + PD markers**
- **Extensive experience with sample processing and shipping**
 - **Covance Singapore, Cenetron US**
 - **World Courier, Marken**
- **Examples**
 - **Repeat Biopsy processing**
 - **Cell stimulation**
 - **FACS**

Imaging Capabilities

- Routine imaging
 - CT
 - MRI
 - Functional MRI
 - Ultrasound
 - Nuclear Medicine
 - PET
- Experimental imaging

Recent Success Stories

INFORM -1

Oral combination therapy with a nucleoside polymerase inhibitor (RG7128) and danoprevir for chronic hepatitis C genotype 1 infection (INFORM-1): a randomised, double-blind, placebo-controlled, dose-escalation trial

Edward J Gane, Stuart K Roberts, Catherine A M Stedman, Peter W Angus, Brett Ritchie, Rob Elston, David Ipe, Peter N Morcos, Linda Baher, Isabel Najera, Tomi Chu, Uri Lopatin, M Michelle Berrey, William Bradford, Mark Laughlin, Nancy S Schulman, Patrick F Smith

www.thelancet.com Published online October 15, 2010 DOI:10.1016/S0140-6736(10)61384-0

- Recruited 90% of patients (80)
- 14 days in-house
- Setting new regulatory standard
- New Hepatitis C treatment paradigm

Hepatitis B

- Treatment-naive Asian male subjects with E antigen positive chronic Hep B
- Initially back up site for sites in Singapore/Taiwan
- Recruitment
 - Taiwan 1
 - Singapore 5
 - Auckland 16

Recent Success Stories

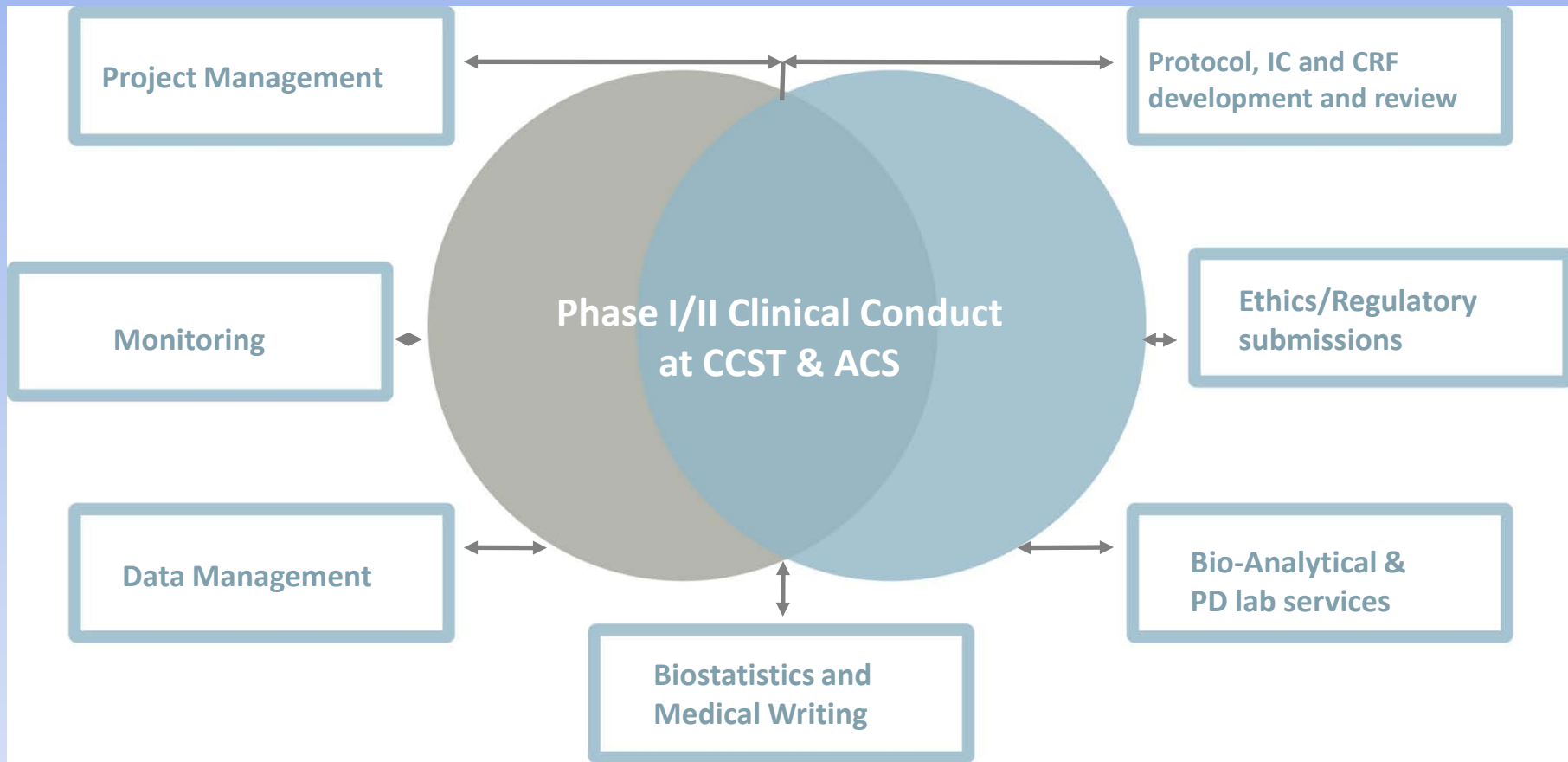
**Comparison of Subcutaneous and Intravenous Administration of Trastuzumab:
A Phase I/Ib Trial in Healthy Male Volunteers and Patients with HER2-Positive
Breast Cancer**

Chris Wynne, Vernon Harvey, Christian Schwabe, Devonie Waaka, Christine McIntyre,
and Beate Bittner*

From Christchurch Clinical Studies, Christchurch, New Zealand (Dr Wynne, Dr Waaka);
Auckland Clinical Studies, Auckland, New Zealand (Dr Harvey, Dr Schwabe); and
F. Hoffmann-La Roche Ltd., Basel, Switzerland (Dr McIntyre, Dr Bittner)

- 120 Healthy volunteers, 50 patients
- Collaboration between CCST and ACS

Tailored to Need



Why Here?

- Physician-led
- Collaboration with local world-class researchers
- Ability to perform complex early phase research
 - in healthy volunteers
 - in patient groups across multiple therapeutic areas
 - Analytical and imaging capability
- Flexibility and adaptability
- Favourable but robust regulatory environment

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