

Adelphi

ADELPHI VALUES



Patient-Centered  
Outcomes

# Adelphi Values Patient-Centred Outcomes

Life as a Statistician at Adelphi Values PCO

# Introduction

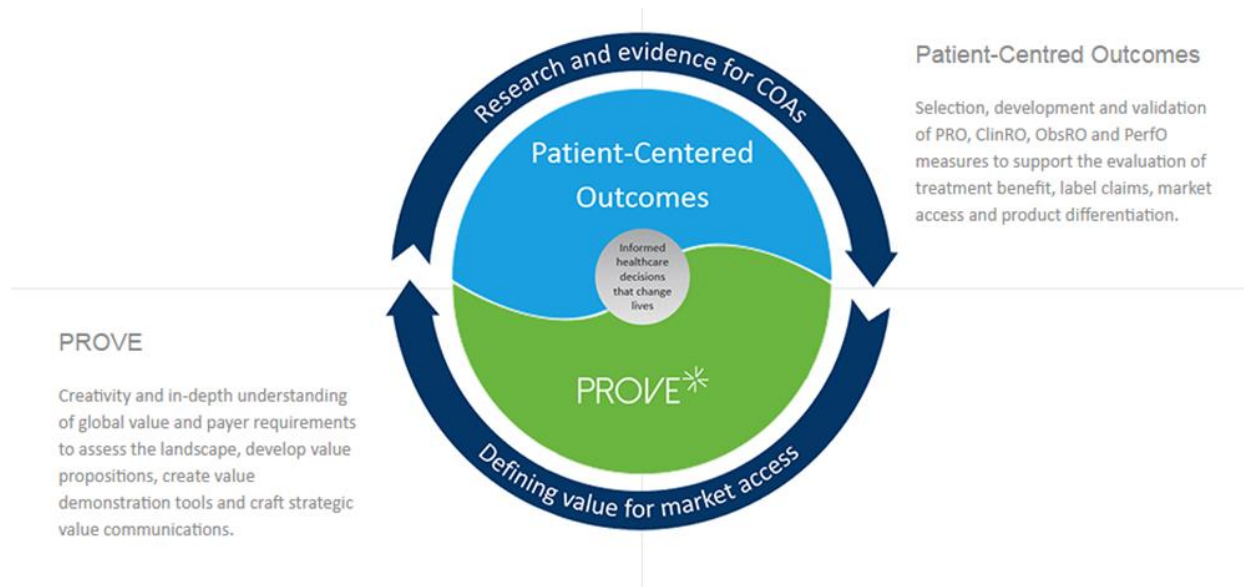
# My education and career pathway

- > Biomedical Science (MBiomedSci) at University of Sheffield
  - Particular interest in bioinformatics and data analysis
  - Graduate teaching assistant for bioinformatics modules and R programming
- > Joined Adelphi Values as a Research Associate (non-statistician) in 2020 and joined the Statistics and Programming team in 2022 as Statistics Research Manager.
- > MSc in Medical Statistics from the University of Leicester (part-time alongside work)
  - To be completed by end of 2024

# Adelphi Values...

## Who we are

- > Adelphi Values is a leading health outcomes consultancy with offices in the UK (**Bollington, Macclesfield** and London) and US (Boston) that works with a wide range of pharmaceutical companies. We comprise two practices:



- > Our purpose is to improve patients' lives by informing healthcare decisions

# Who we work with...



# Statistics and Programming Team

- > The Adelphi Values **Statistics and Programming team** comprises of around **24 people in the UK** including:
  - 10 Statisticians (at varying levels)
  - Psychometricians
  - SAS programmers

# What we do

## The role of a Statistician

# The data we work with

- > We analyse data collected from **patient-reported outcomes (PROs)**
  - A **PRO** is a measurement based on a report that comes directly from the patient about the status of the patient's health condition
  - PROs may serve as **primary, secondary or exploratory endpoints** in Phase II/III trials
  - Regulators (e.g. FDA) often request PRO data to support the **risk-benefit assessment** when deciding to approve treatments



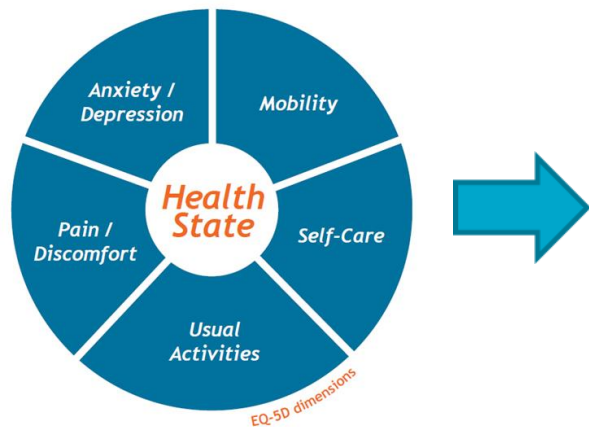


# What the Statistician role involves

- > Writing **Statistical Analysis Plans**
- > **Production of statistical analysis, tables and figures in SAS and R**
- > **Performing and/or reviewing statistical analyses** and providing input on the **interpretation of results**, with awareness of regulatory requirements
- > Providing input on the statistical elements of **study reports, publications**, and other deliverables
- > Utilising a number of **advanced statistical methods**
- > Serving as a statistical consultant internally for Adelphi Values and externally for clients
- > Our clients ask us a lot of questions that impact their studies and how they collect and interpret the data - we are the **experts**.

# An example PRO

## The EQ-5D-5L



- Level 1: indicating no problems
- Level 2: indicating slight problems
- Level 3: indicating moderate problems
- Level 4: indicating severe problems
- Level 5: indicating extreme problems

- > The responses from each patient is then converted into a **weighted utility score**, with scores ranging between 1 (perfect health) to less than 0. Negative scores represent a health state that is considered worse than being dead
- > In addition, the EQ-5D includes a **VAS**, which allows respondents to rate their own current health on a scale of 0 to 100, with 0="worst imaginable" health to 100="best imaginable" health

# What methods we use regularly



Survival models (time to an event e.g., a deterioration in PRO score)



Longitudinal models (repeated measures modelling of PRO scores at each visit)



Missing data is a major challenge when analysing PRO data

Evaluating the extent and impact of missing data  
Reasons for missing data



Several methods of dealing with missing data, including:

Multiple imputation (replacing missing values)  
Advanced sensitivity analysis methods such as joint modelling

**20** Health-related quality of life (HRQoL) with first-line (1L) nivolumab (NIVO) plus ipilimumab (IPI) vs chemotherapy (chemo) in patients (pts) with microsatellite instability-high (MSI-H)/mismatch repair-deficient (dMMR) metastatic colorectal cancer (mCRC): CheckMate 8HW

S. Lonardi<sup>1</sup>, T. André<sup>2</sup>, D. Arnold<sup>3</sup>, R. Garcia-Carbonero<sup>4</sup>, M. Chalabi<sup>5</sup>, M.E. Elez Fernandez<sup>6</sup>, H.J. Lenz<sup>7</sup>, L.H. Jensen<sup>8</sup>, R. Joshi<sup>9</sup>, J.M.L. Roodhart<sup>10</sup>, T. Yoshino<sup>11</sup>, M. Dixon<sup>12</sup>, S.I. Blum<sup>13</sup>, J. Sims<sup>14</sup>, R. Lawrance<sup>15</sup>, F. Taylor<sup>16</sup>, T. Chen<sup>17</sup>, E. Cela<sup>18</sup>, L. Jin<sup>19</sup>, E. Van Cutsem<sup>20</sup>

> Recent publication in colorectal cancer applying **longitudinal modelling** of PRO scores

Table: 20

Wk 21 HRQoL	NIVO + IPI	Chemo	LS MD (95% CI)
	LS mean change from BL (95% CI)		
<b>EORTC QLQ-C30</b>	<b>n = 120</b>	<b>n = 30</b>	
GHS <sup>a</sup> (5.0)	9.0 (5.6, 12.4)	-1.6 (-7.2, 4.0)	10.6 <sup>c</sup> (4.8, 16.4)
Physical functioning <sup>a</sup> (6.0)	4.9 (2.0, 7.7)	-2.4 (-7.4, 2.5)	7.3 <sup>c</sup> (1.9, 12.7)
Fatigue <sup>b</sup> (6.0)	-7.6 (-11.6, -3.5)	9.3 (2.3, 16.2)	-16.8 <sup>c</sup> (-24.3, -9.3)
<b>EQ-5D-3L</b>	<b>n = 119</b>	<b>n = 27</b>	
VAS <sup>a</sup> (7.0)	9.3 (5.9, 12.6)	2.4 (-3.1, 8.0)	6.8 (1.1, 12.6)
Utility Index <sup>a</sup> (0.08)	0.10 (0.06, 0.14)	0.04 (-0.02, 0.11)	0.06 (-0.01, 0.12)

<sup>a</sup>Positive change = improvement

<sup>b</sup>Negative change = improvement

<sup>c</sup>Prespecified MID was reached

# PRO-CTCAE – recent project example

Core PROs in oncology trials should include disease-related symptoms, physical functioning, impact of side effects and symptomatic adverse events (AE)

The PRO-CTCAE is a PRO developed to evaluate symptomatic adverse events, in which patients can self-report their AEs (rather than the clinician)

There are different methods available to analyse and present these data

# Interactive visualisations

## PRO-CTCAE Visualisation


Baseline Adjusted Worst Score

Item Response Frequencies

Item  
Memory Problems

Exclude Missing

Visit Range



A horizontal timeline slider with a blue bar. The bar starts at a marker labeled '1' and ends at a marker labeled '21'. Below the bar, numerical markers are placed at intervals of 5: 1, 6, 11, 16, 21, 26, 31, 36, 41, 46.



# Applying for a role at Adelphi Values PCO

# Life at Adelpi

- > Social events
- > Free gym membership
- > Private healthcare
- > Pension scheme
- > Graduate academy
- > Leadership programmes
- > Staff training and development
- > Scope for travel on certain projects
- > Conference attendance



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# Key skills required as a Statistician

 Masters in medical statistics, applied statistics or a related field

 Ability to communicate results (verbally and written) to non-statisticians

 Analytical skills

 Attention to detail

 Problem-solving skills

 Enjoy learning new things

# Tips on how to approach hiring process



Where to look for jobs:

LinkedIn  
University careers services



Knowing what's out there

There are roles in areas you wouldn't have thought existed in the first place!



Be aware of the careers available to statisticians

CROs (Contract research organisation like Adelphi)  
Pharmaceutical industry  
Academia

# How to apply

- > Positions within PCO are advertised on the careers section of our website
  - <https://www.adelphivalues.com/careers/>
- > Positions are also advertised on LinkedIn

# QR code to register interest

