



Green Park Collaborative

A partnership for innovation and effectiveness

The metrics of value of NASH interventions for patients and payers

The coreNASH project update

Elizabeth Clearfield | 11 July 2019 | Paris NASH Meeting



Green Park Collaborative is a major initiative of the Center for Medical Technology Policy

coreNASH Sponsors



Novartis



Conflict of Interest

- I have no conflict of interest to declare



coreNASH



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Green Park Collaborative
A partnership for innovation and effectiveness

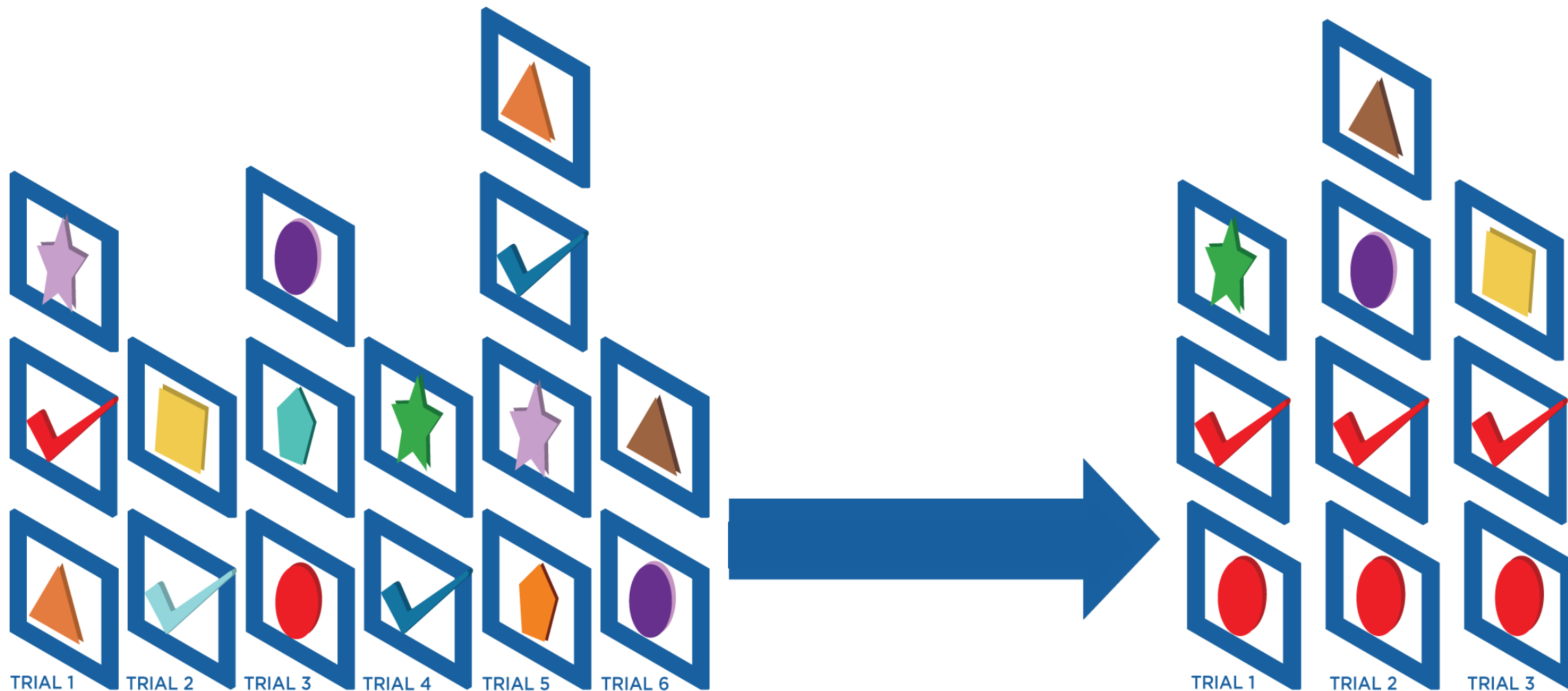
OAC
Obesity Action Coalition

Core Outcome Sets (COS)

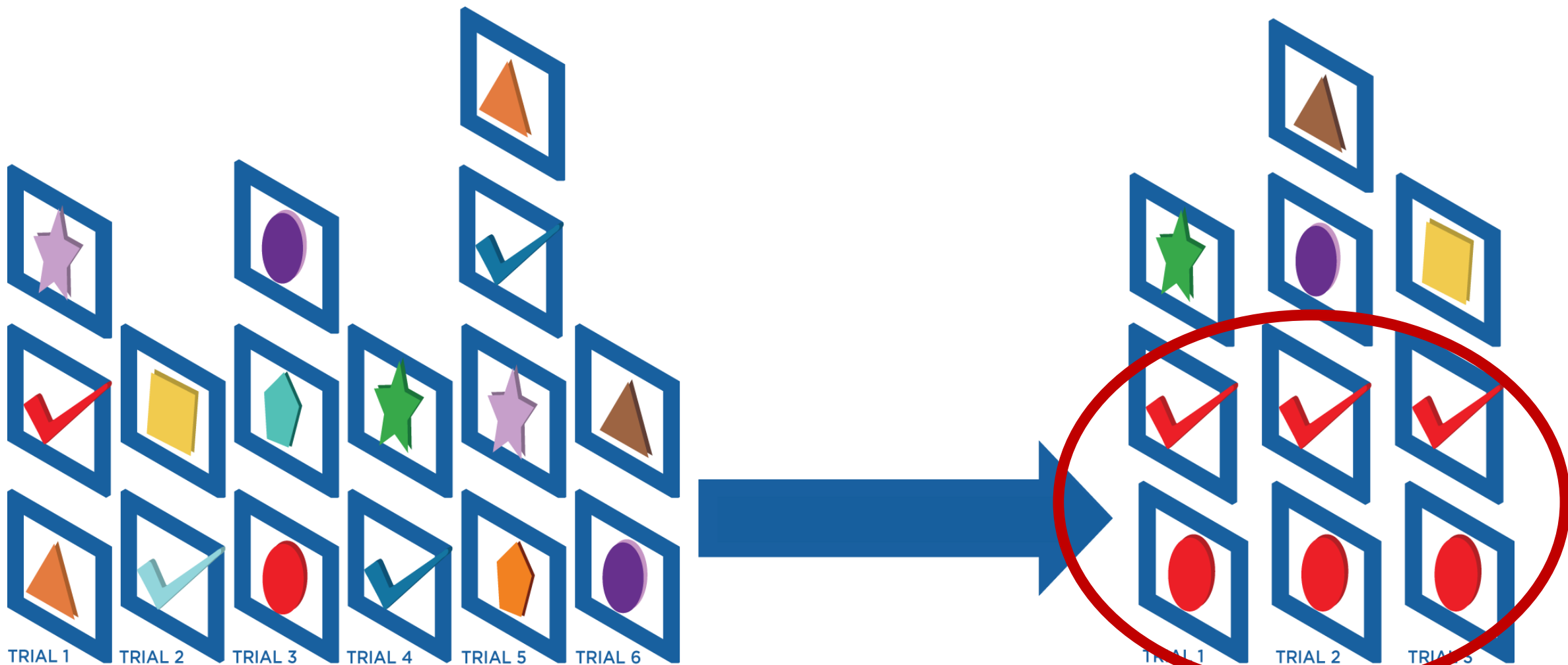
“An agreed standardised set of outcomes that should be measured and reported, as a minimum, in all clinical research in specific areas of health or health care”

Definition from the COMET (Core Outcome Measures in Effectiveness Trials) Initiative

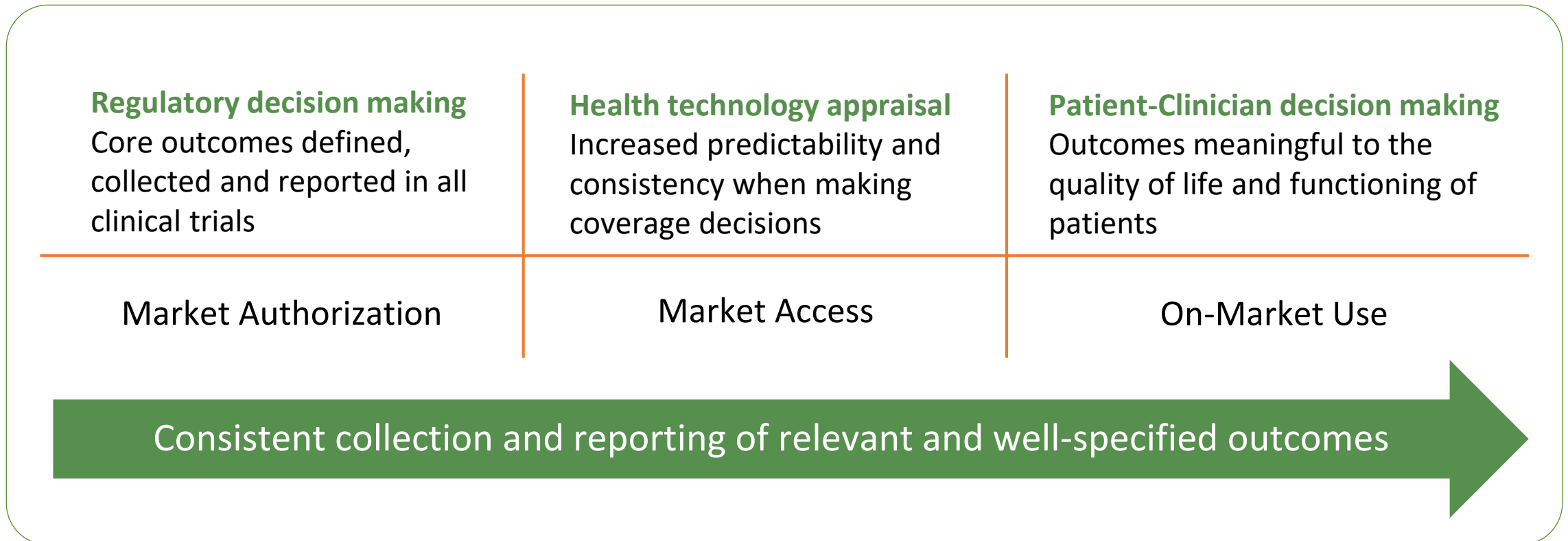
Why use a core set?



Why use a core set?



Where are core outcomes useful?

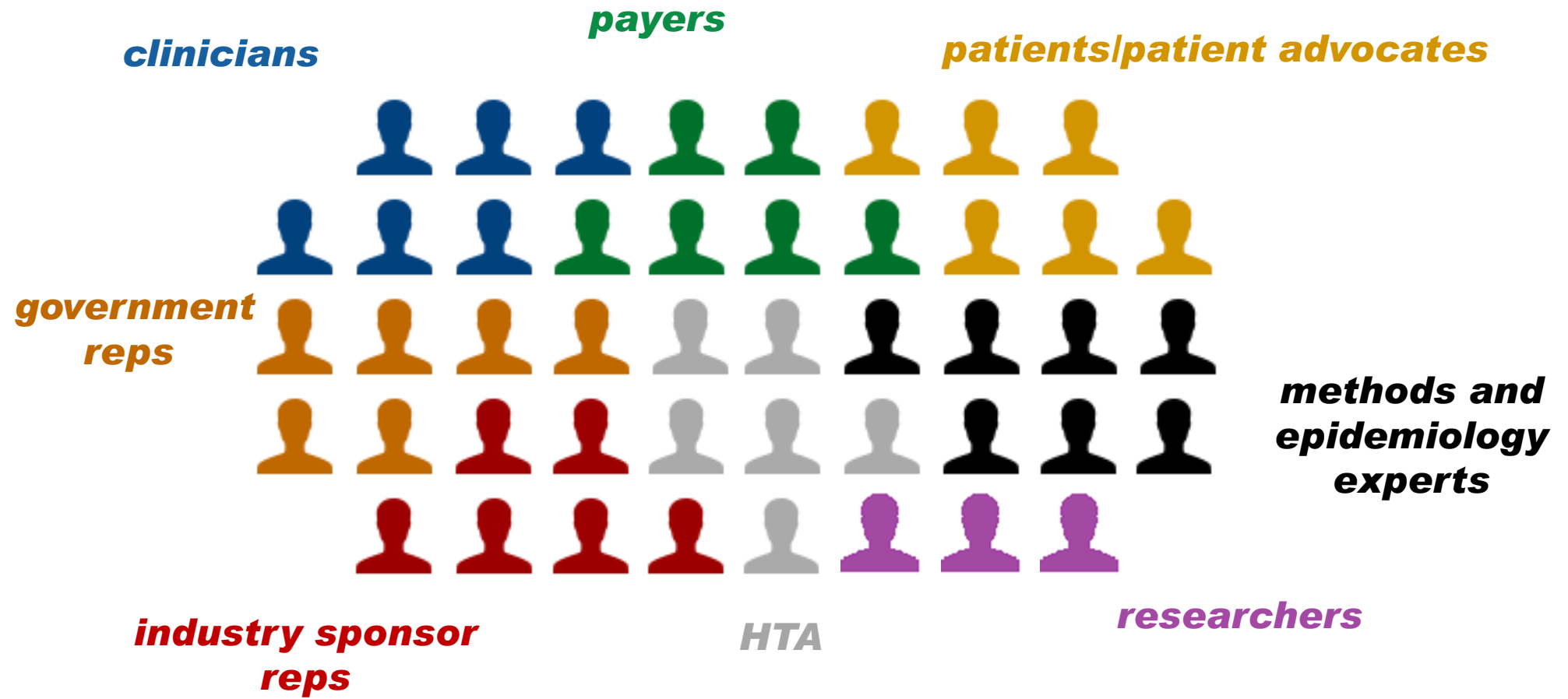


Skinner, Clearfield, Iorio, Tunis. Comparing Outcomes Across Clinical Trials: Core Outcome Set for Hemophilia Gene Therapy as a Model for Other Diseases (2017). DIA Global Forum Vol. 9 Issue 5

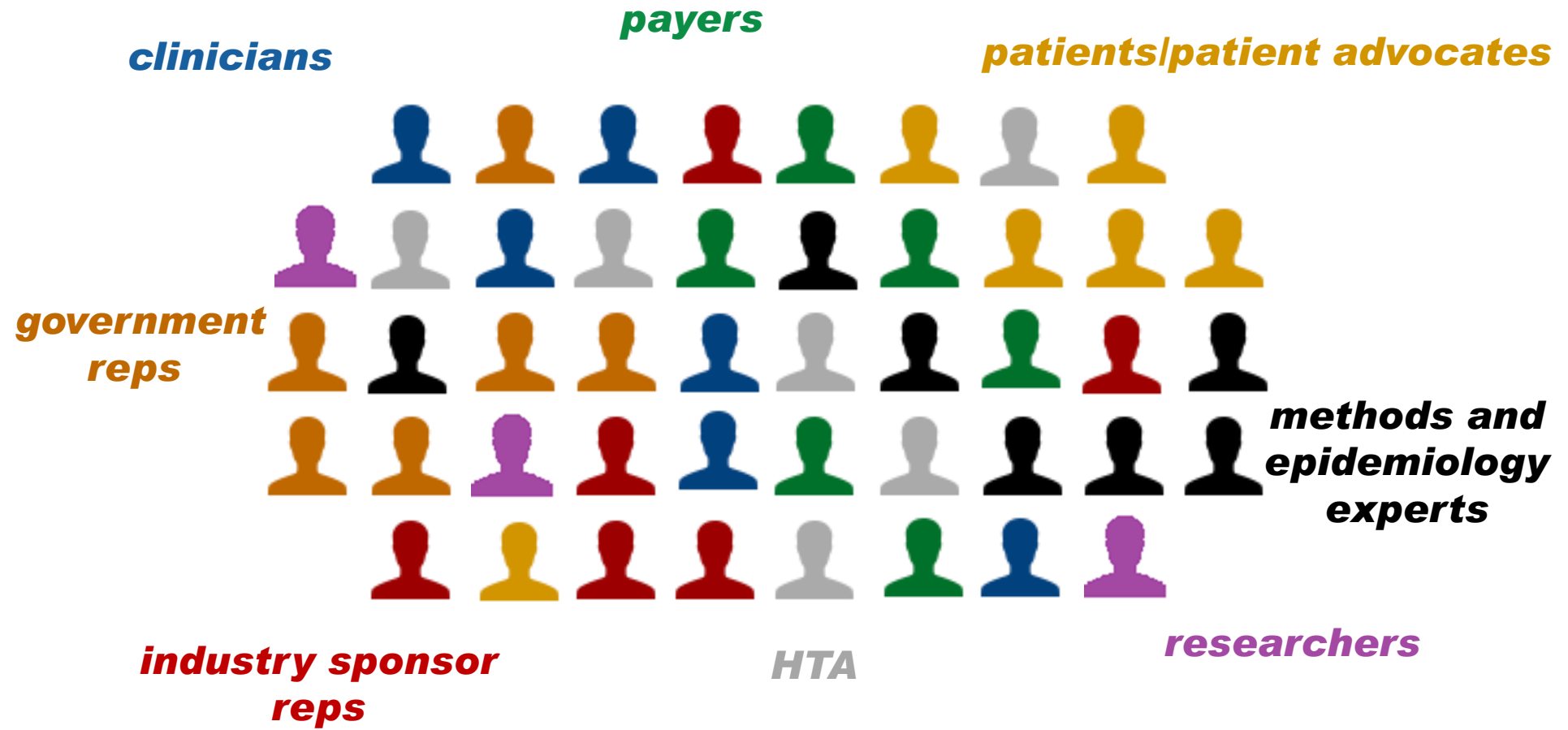
Why now?

- NASH treatment landscape is changing
- Outcomes associated with new treatments may be different than outcomes used in the past
- Important time to include perspective of people who make decisions about the treatments
 - Patients
 - Payers
 - Health technology assessors

Multi-stakeholder by Design



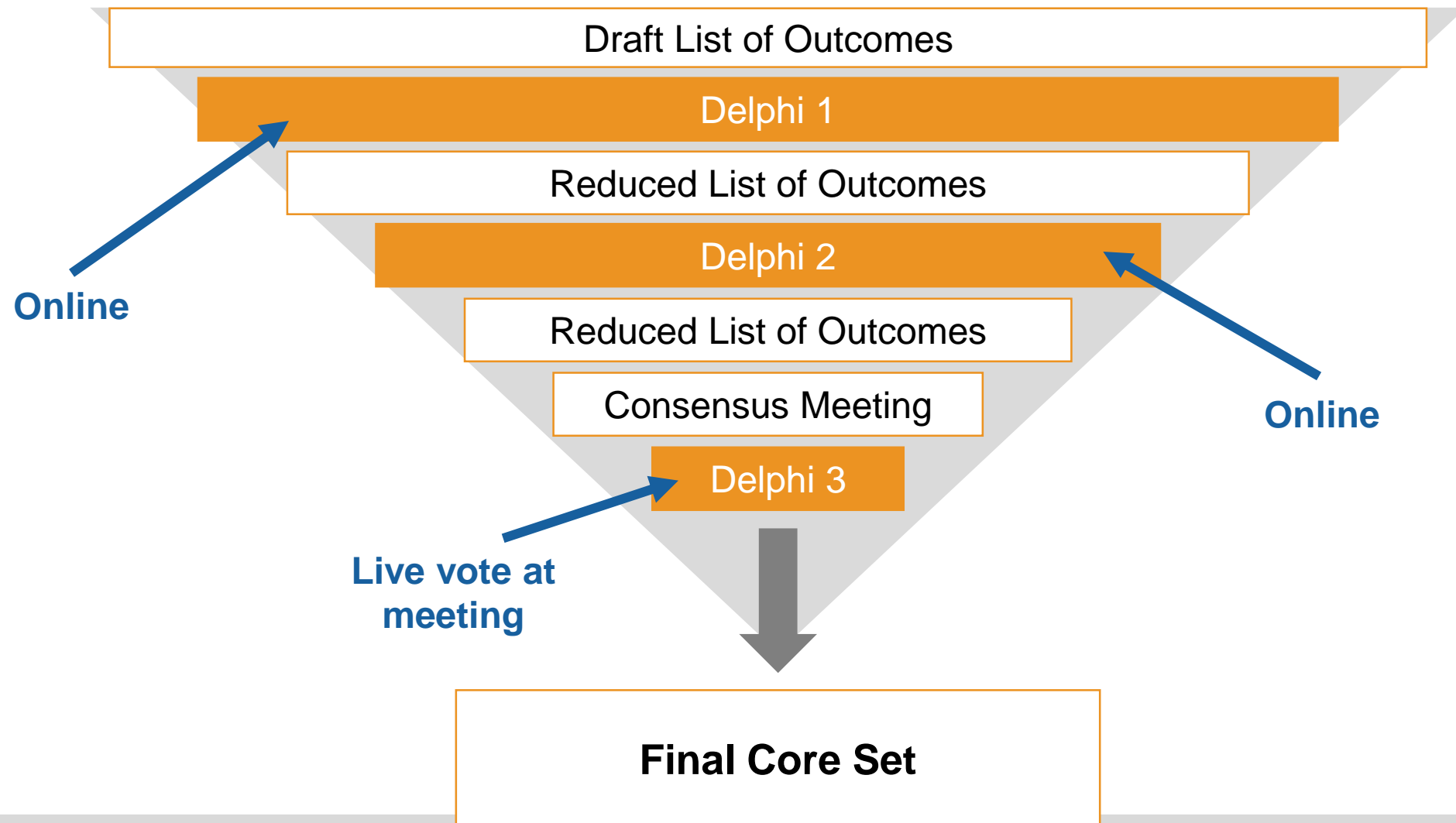
Multi-stakeholder Process



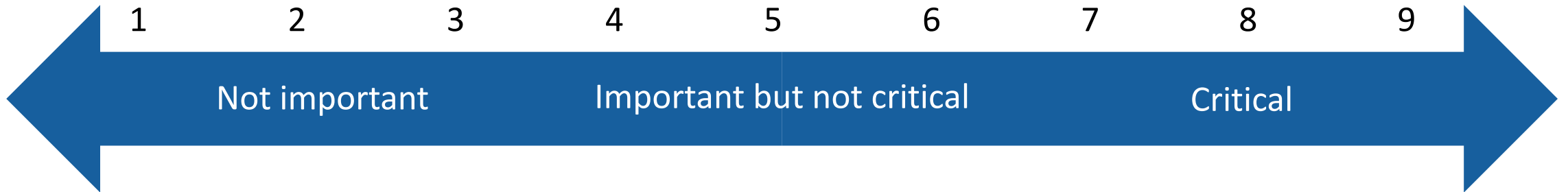
coreNASH Participants

- 47 different organizations are represented in this project
- To briefly summarize:
 - 11 pharmaceutical companies with a NASH treatment in development
 - 6 patient organizations/advocacy groups
 - 7 government organizations
 - 10 universities
 - 5 payer organizations

Selecting core outcomes

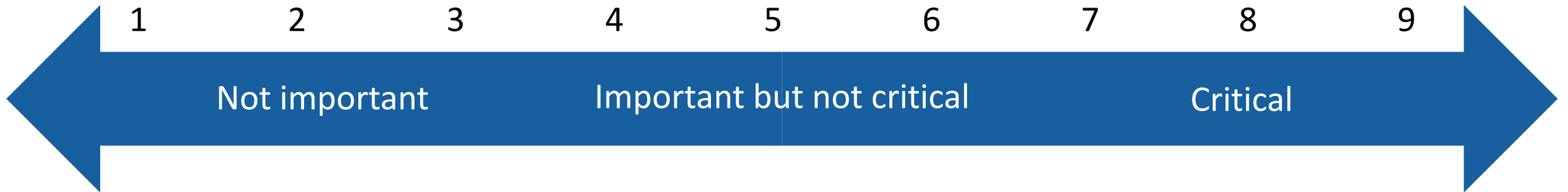


Rating Outcomes & Consensus Rules



High Consensus	≥70% of all voters rated the outcome with a score of 7, 8, or 9
Patient-Important	<70% of all voters rated the outcome 7, 8 or 9, BUT the patient group gave the outcome an average rating of ≥7
Eliminate	<70% of voters rated the outcome 7, 8, or 9, AND the patient group average rating was <7

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Core sets based on disease severity

NASH without cirrhosis

Fibrosis stage F2-F3

NASH with cirrhosis

Fibrosis stage F4

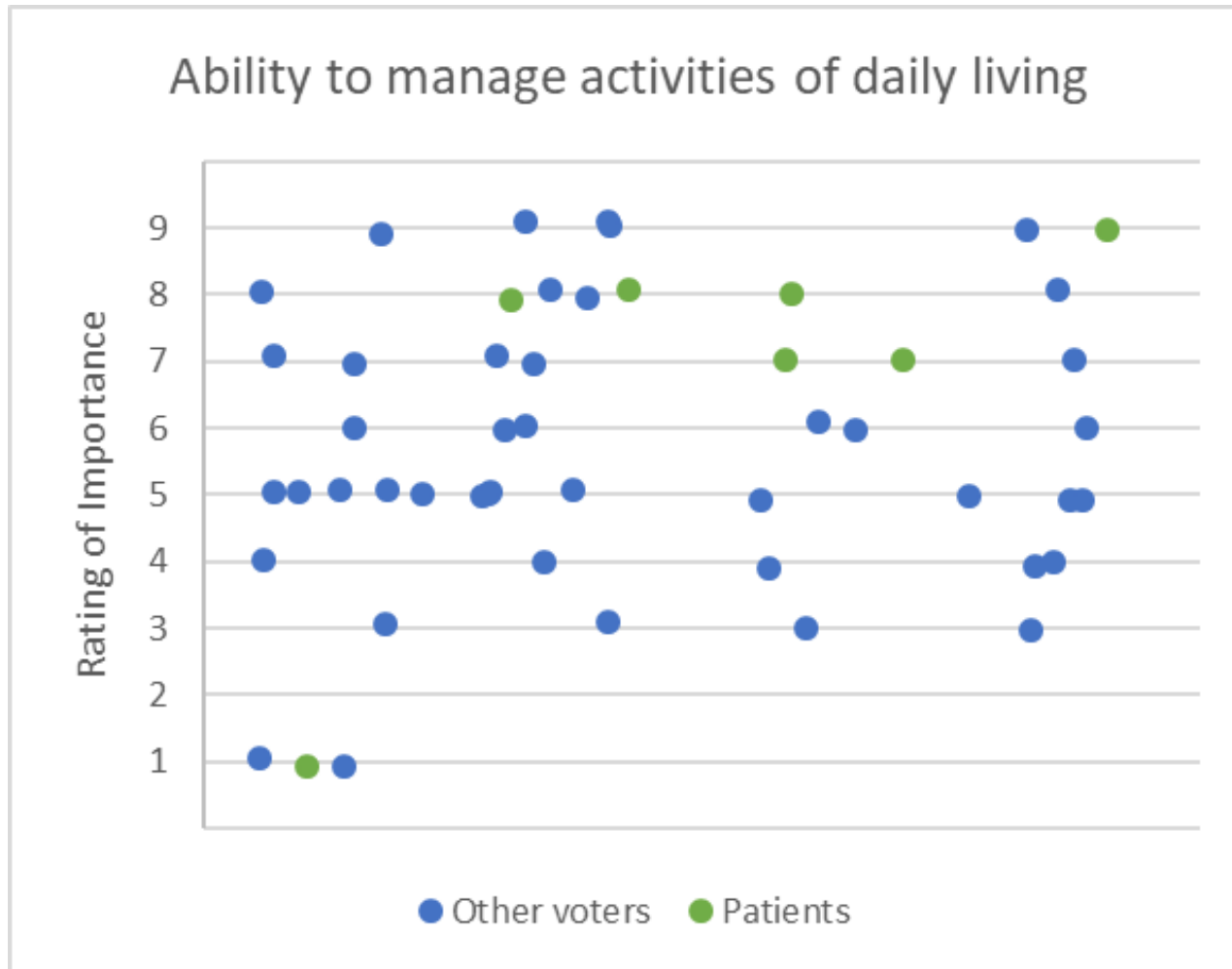
Some examples

- Patient priorities
- Patients voters aligned with other voters
- Payer priorities
- Patients compared with payers

Patient Priorities

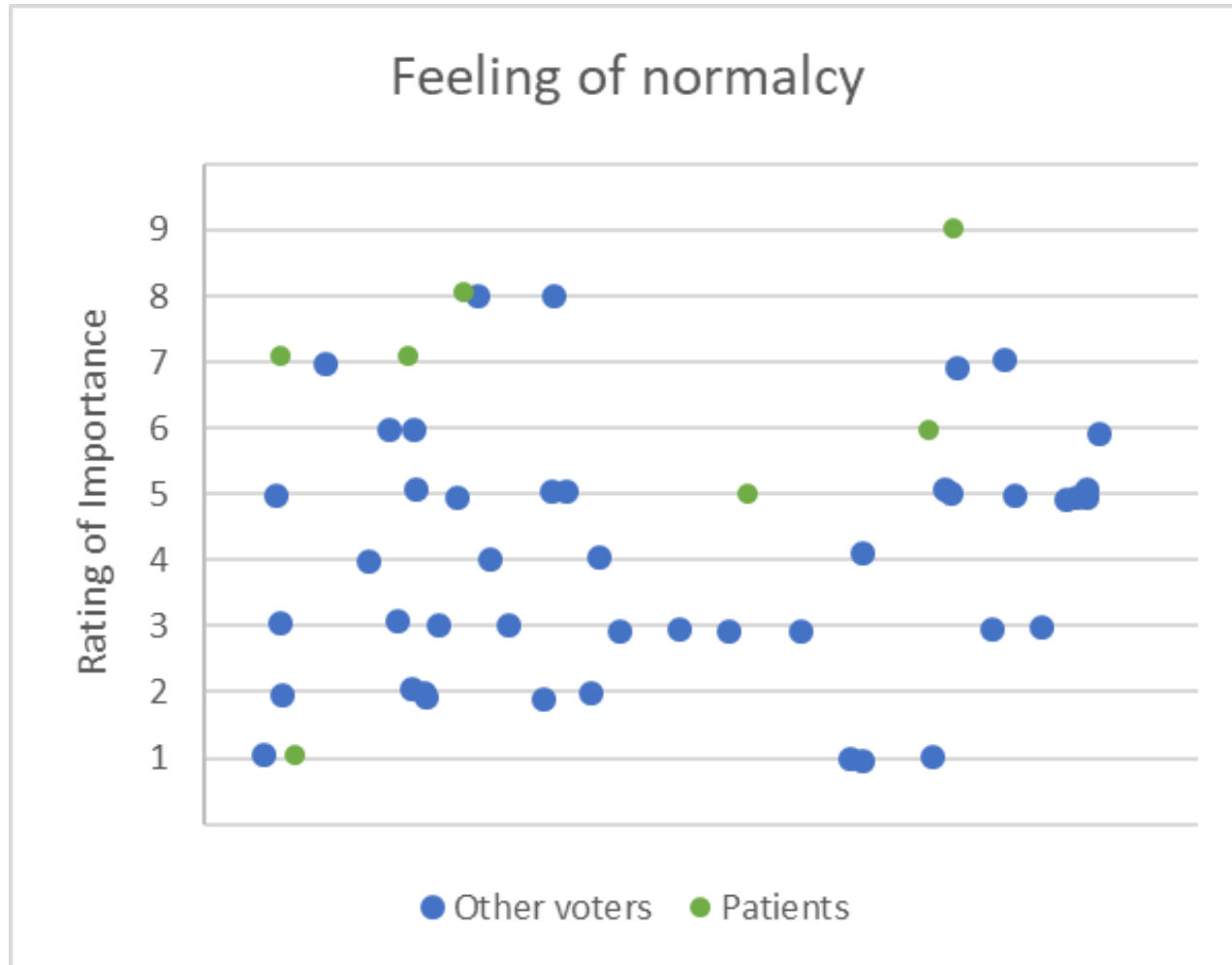
- Gave higher ratings to outcomes dealing with functioning
 - Ability to live life “normally”
- Satisfaction with
 - Treatment
 - Provider

Patient Priorities - Functioning



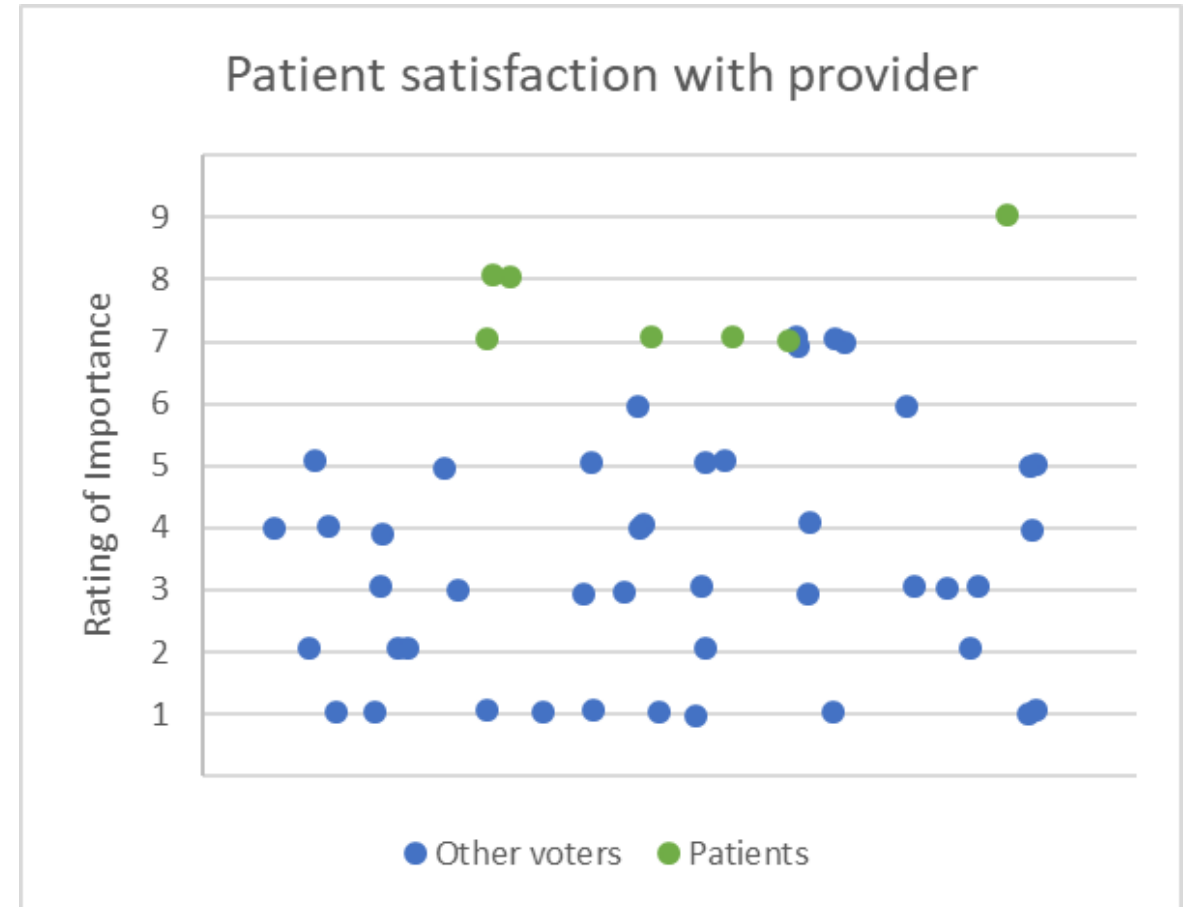
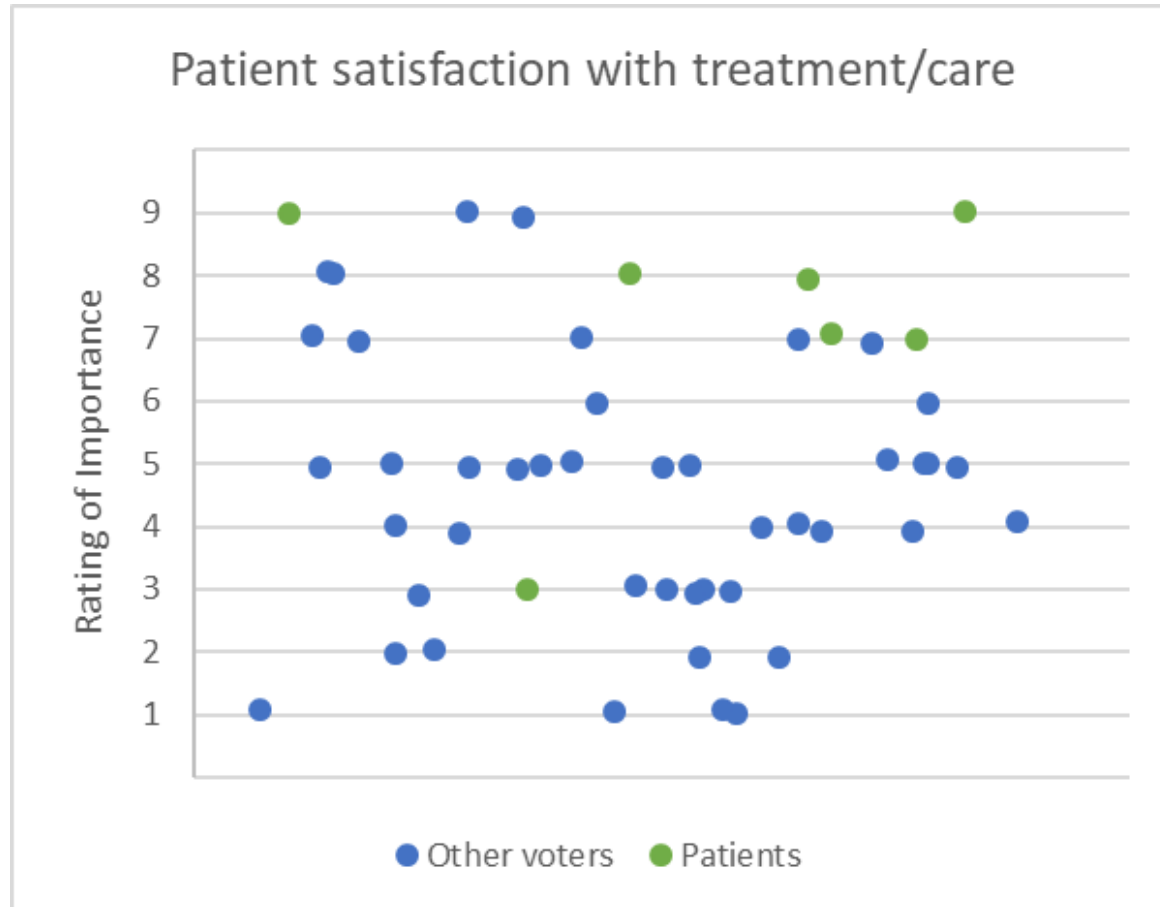
Patient Average Rating: 6.86
Non-patient Average Rating: 5.61

Patient Priorities - Functioning

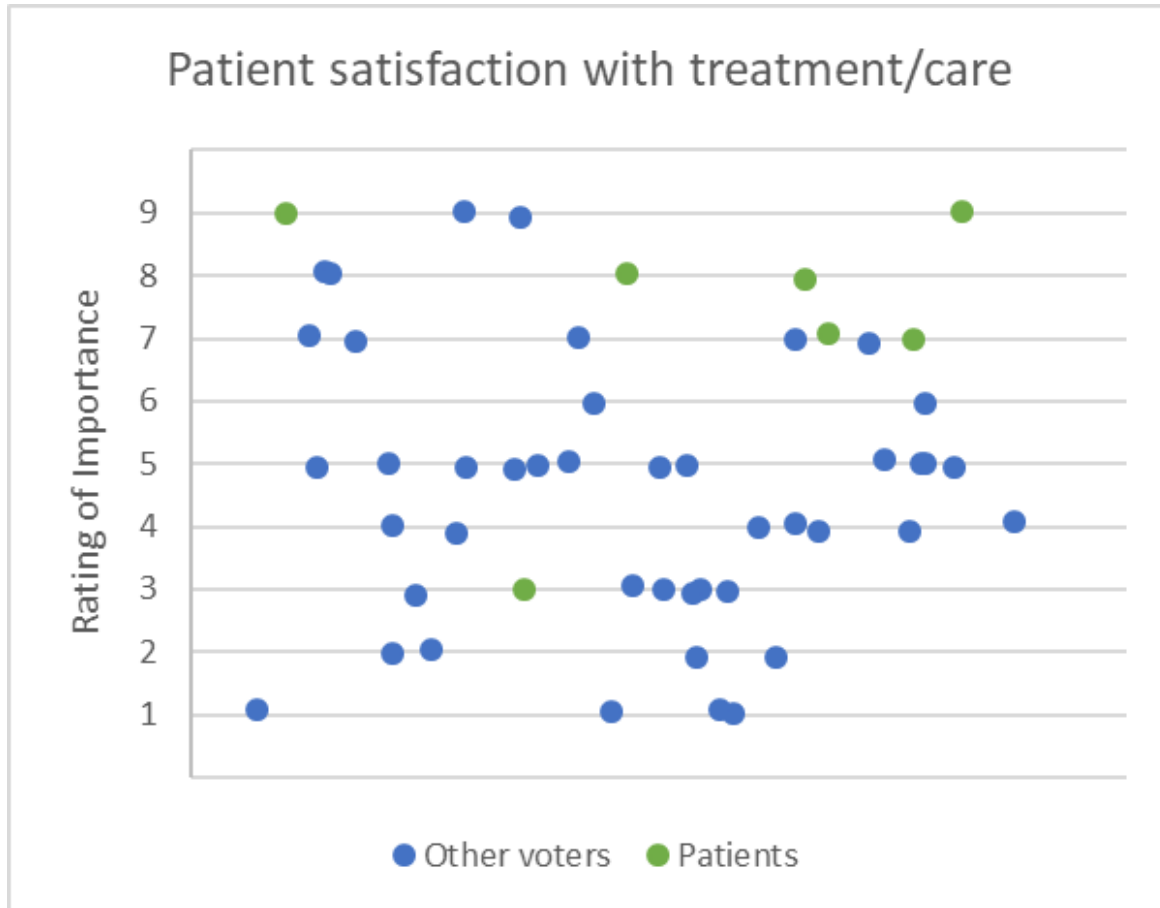


Patient Average Rating: 6.14
Non-patient Average Rating: 4.02

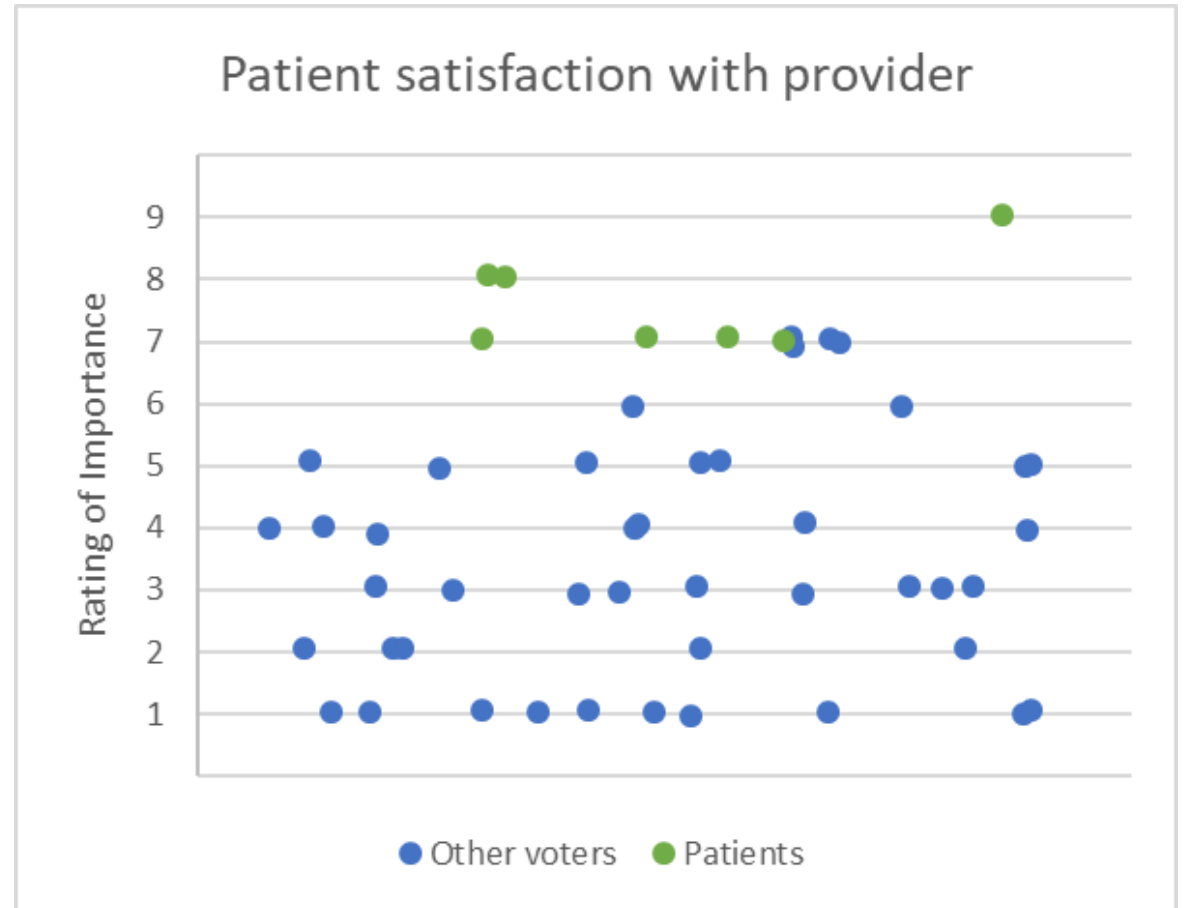
Patient Priorities - Satisfaction



Patient Priorities - Satisfaction



Patient Average Rating: 7.29
Others Average Rating: 4.52

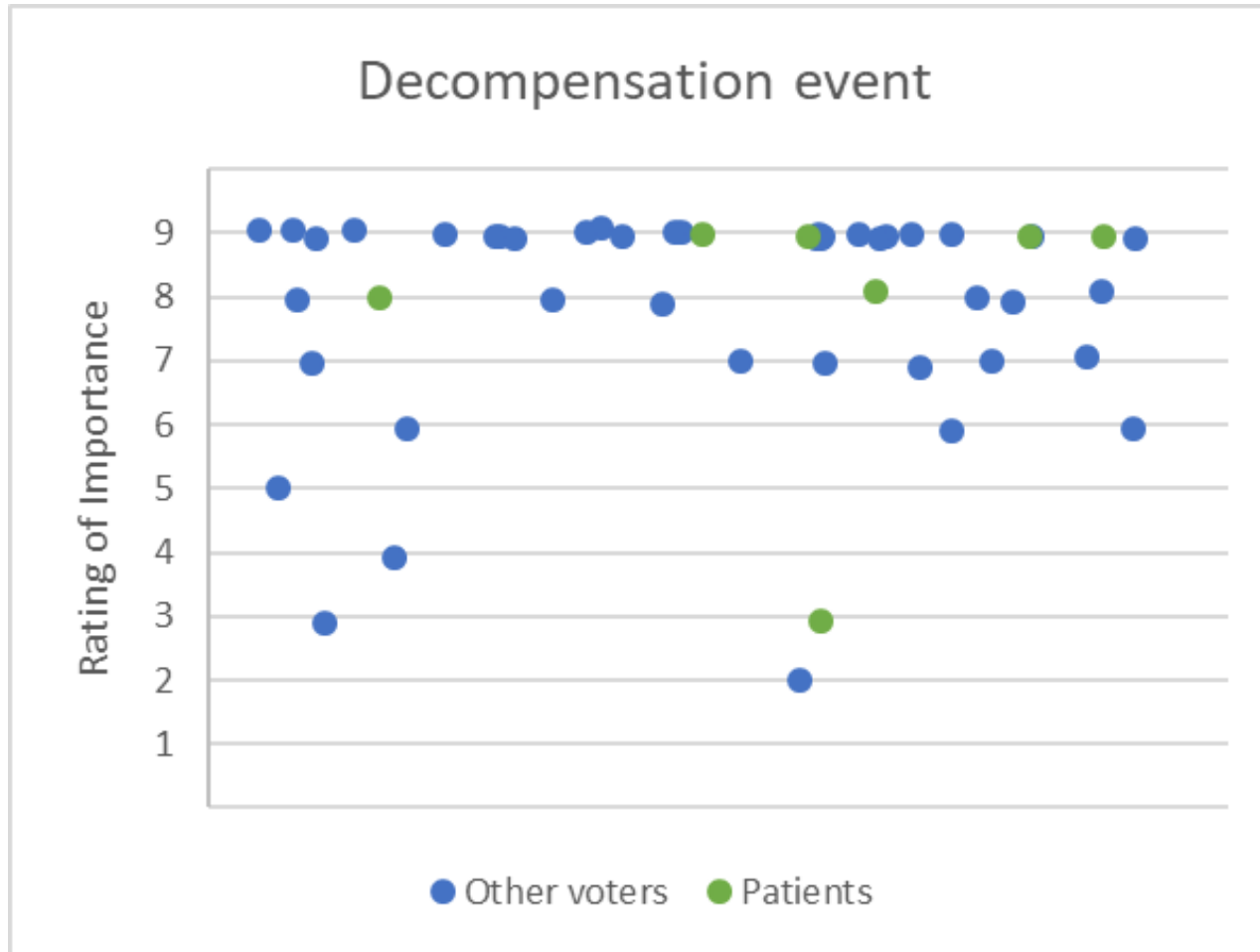


Patient Average Rating: 7.57
Others Average Rating: 3.41

Patients in alignment with other voters

- Outcomes important to the majority of the group
- Clinical outcomes
 - Used to differentiate disease severity
- Patient votes contributed to a high overall average

Patients in alignment with other voters

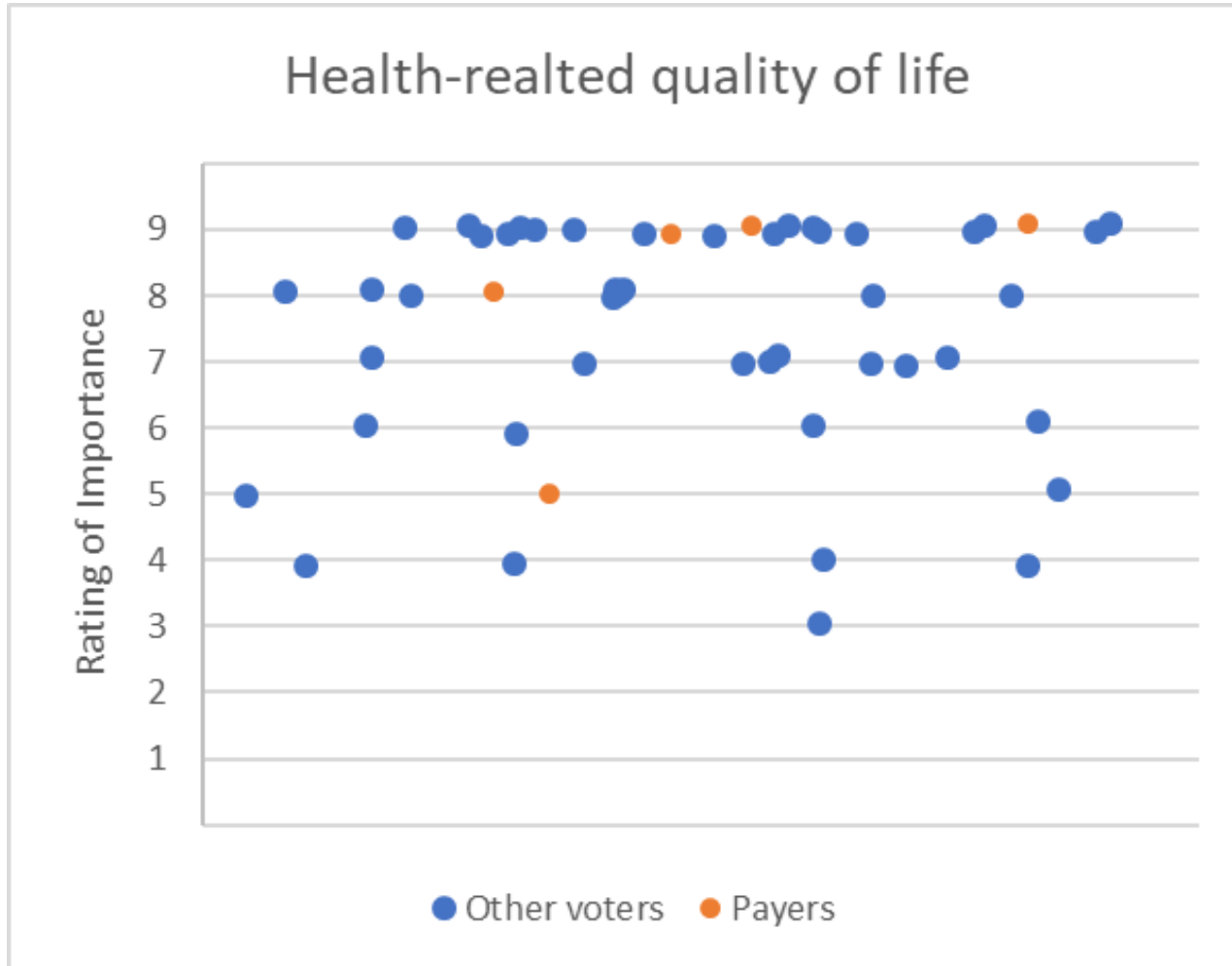


Patient Average Rating: 7.86
Non-patient Average Rating: 7.86

Payer Priorities

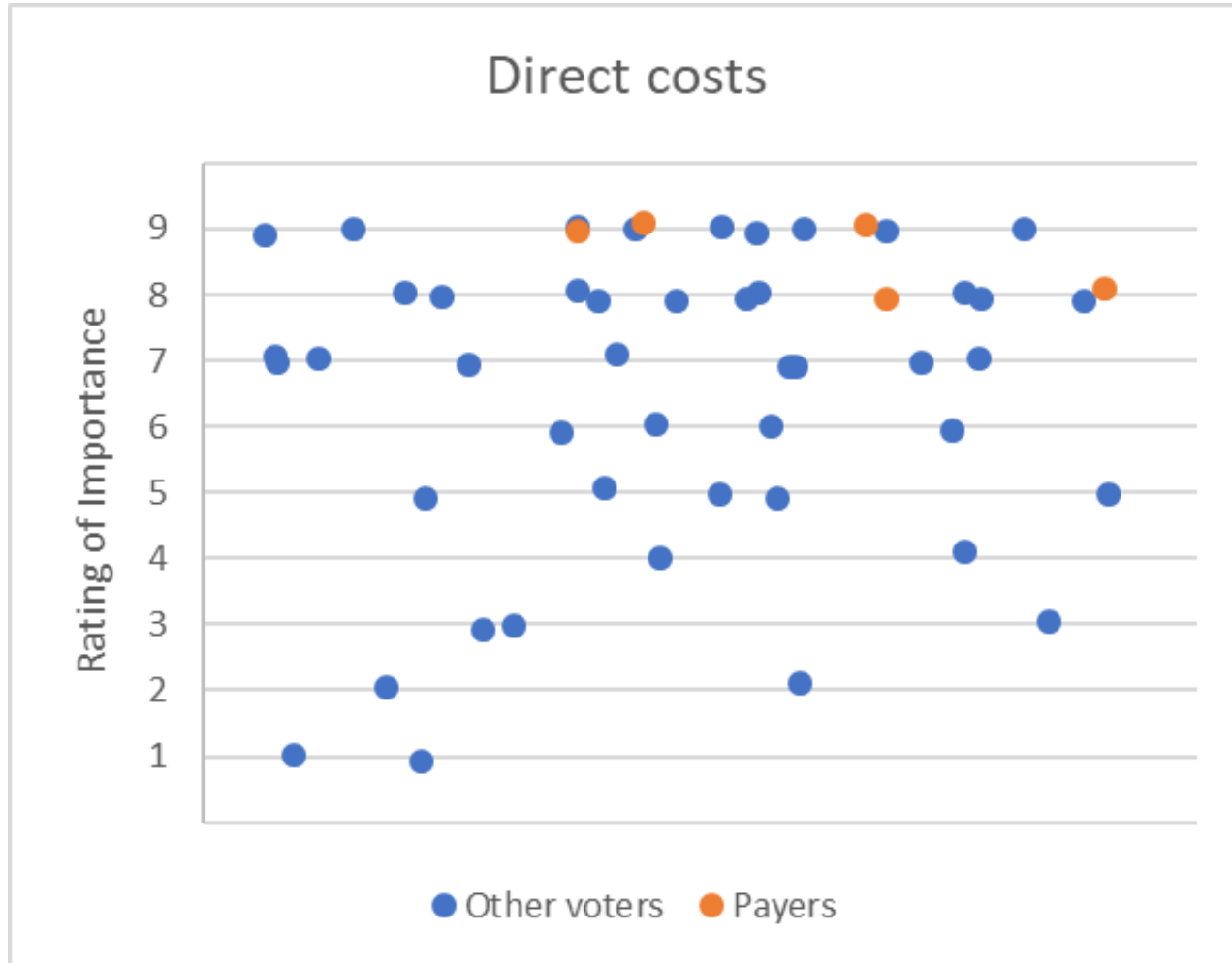
- Highly rated outcomes
 - Quality of life
 - Direct costs
- Low rated outcome
 - Work absenteeism

Payer Priorities



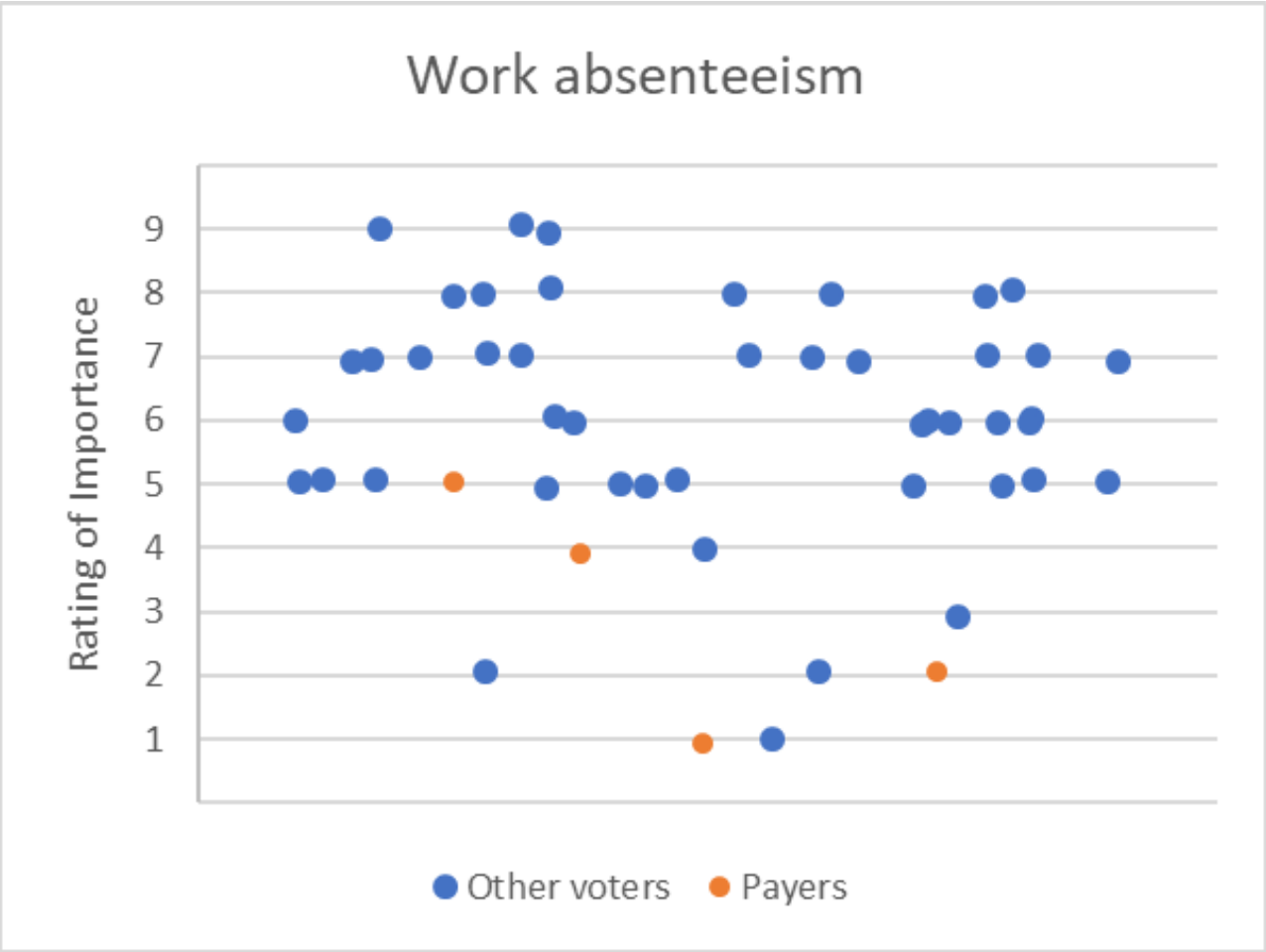
Payers Average Rating: 8.00
Other Voters Average Rating: 7.46

Payer Priorities



Payers Average Rating: 8.60
Other Voters Average Rating: 6.43

Payer Priorities

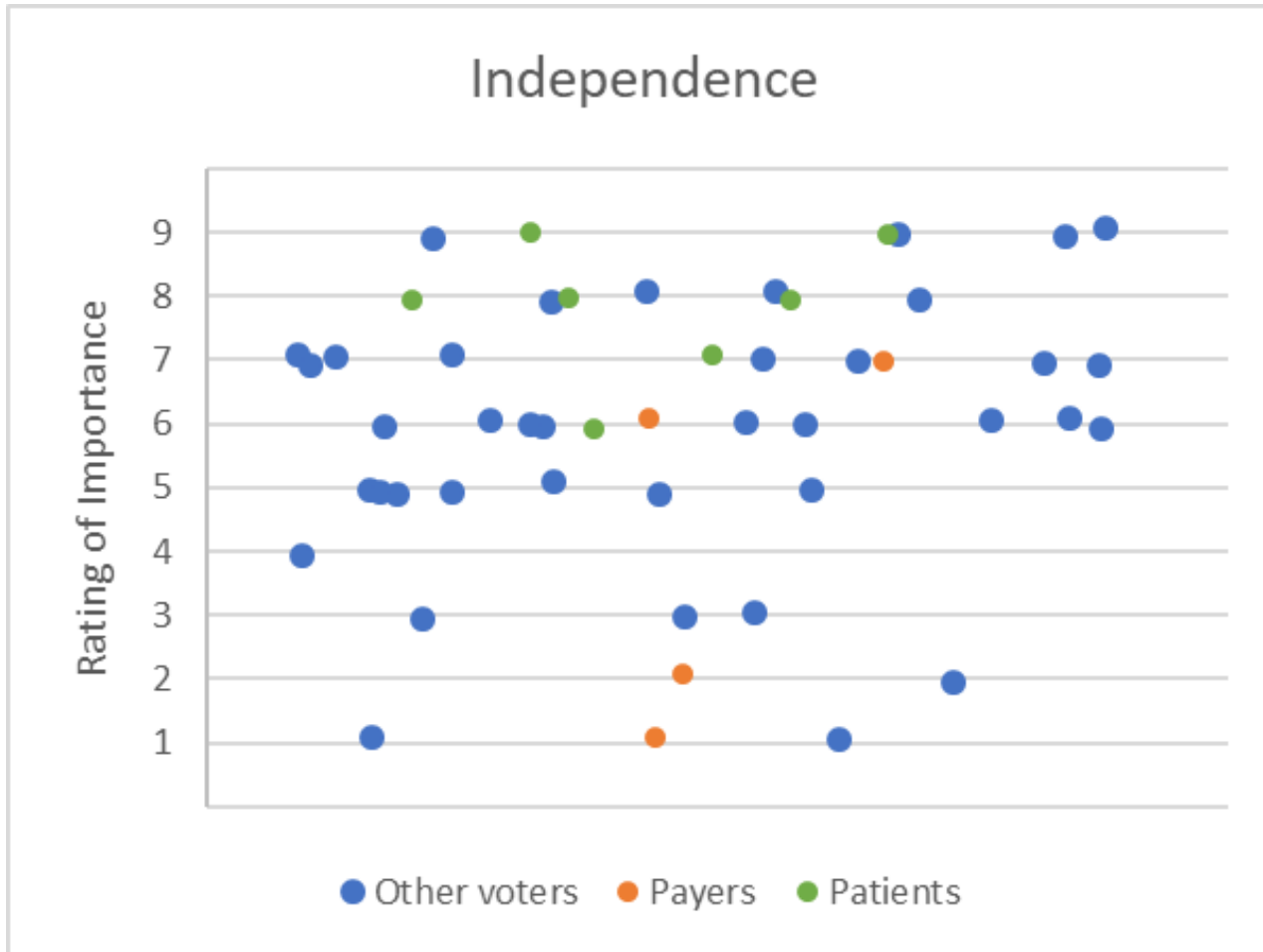


Payers Average Rating: 3.00
Other Voters Average Rating: 6.11

Payers vs Patients

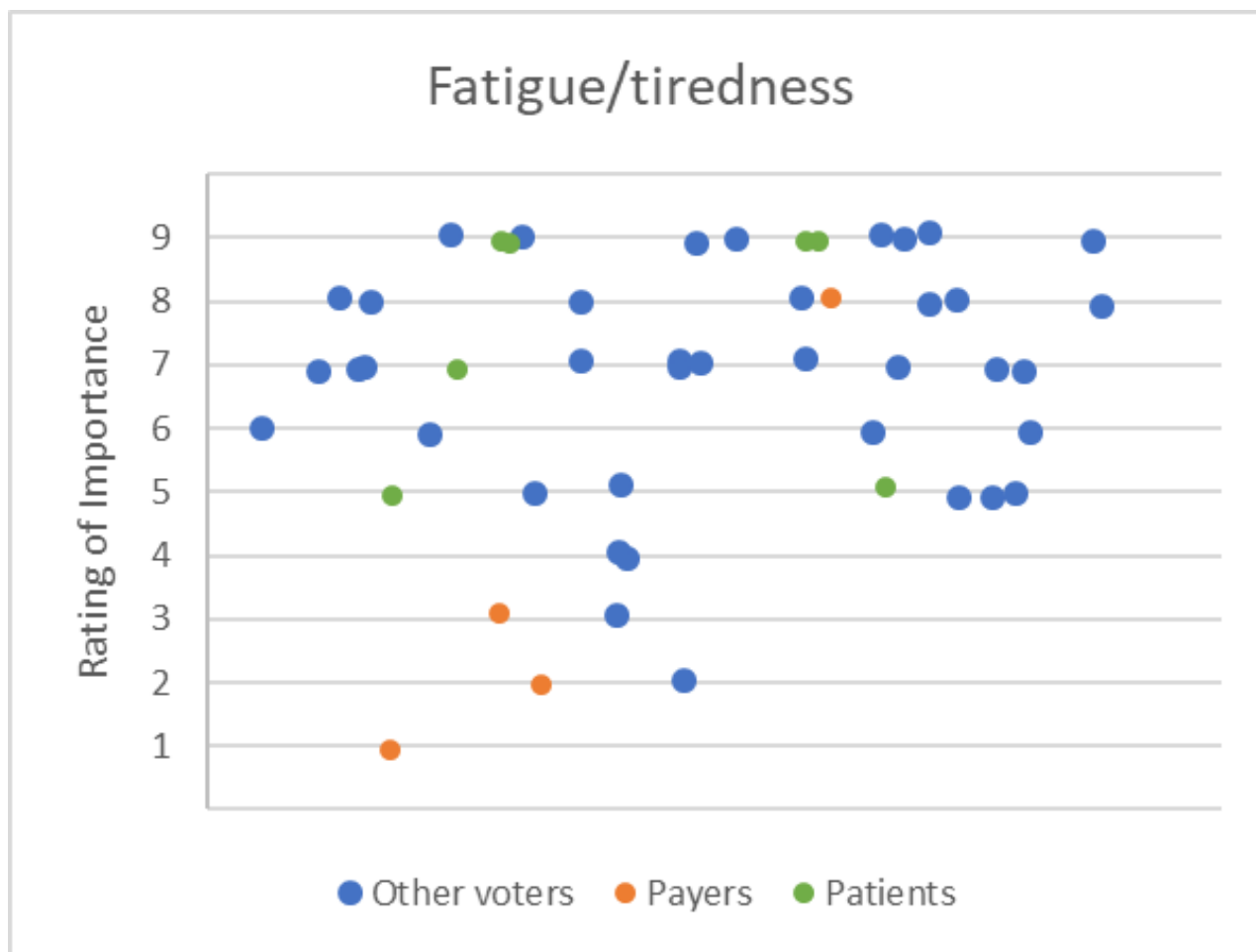
- Outcomes beyond those required for regulatory review
- Do payers and patients vote the same?

Payers vs Patients



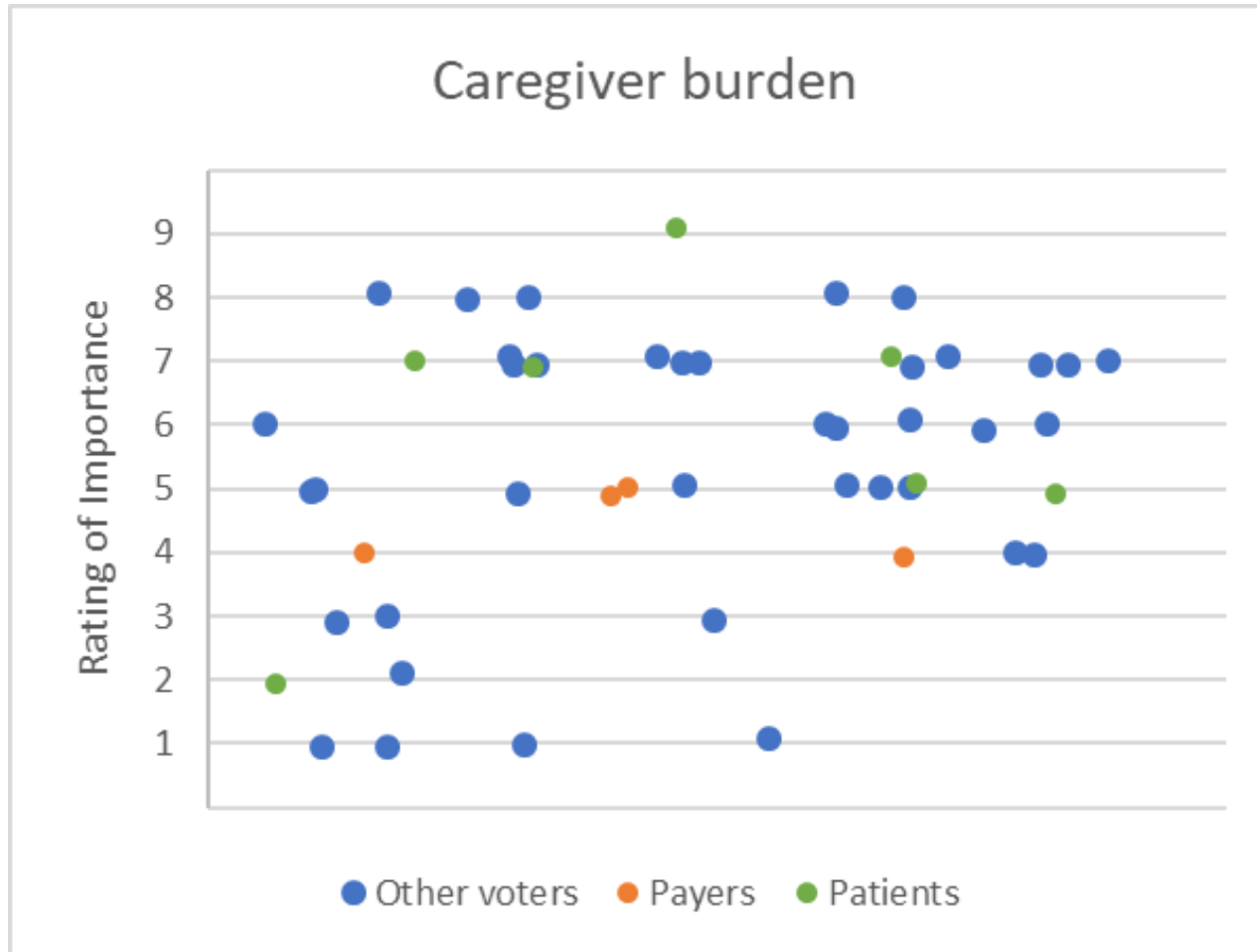
Payer Average Rating: 4.00
Patient Average Rating: 7.86
Others Average Rating: 5.90

Payers vs Patients



Payer Average Rating: 3.50
Patient Average Rating: 7.57
Others Average Rating: 6.85

Payers vs Patients



Payer Average Rating: 4.50
Patient Average Rating: 6.00
Others Average Rating: 5.41