AQC 2016 Survey Research

Final Report of Patient Survey and AQC Member Survey Data

Avoca

THE AVOCA GROUP

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Introduction

Introduction: 2016 AQC Survey Programs

- The 2016 AQC Survey Research Program had two components – AQC's first Patient Survey, and an abbreviated version of the annual Member Survey. Inclusion of the Patient Survey in 2016 was related to AQC's objective to understand clinical research quality, and how it might be improved, from the viewpoint of all key stakeholders.
- The overall objectives of the AQC Patient Survey were to gain an understanding of:
  - the extent to which patients perceive that their medical care providers understand various aspects of the patient experience,
  - patient perceptions of "quality" and value in clinical research, as well as actions by researchers that might positively and negatively impact these perceptions, and
  - factors that drive patients' desires to participate and continue in clinical trials.
- The objective of the 2016 AQC Member Survey was to examine quality topics in a manner that paralleled the Patient Survey, as well as to continue to follow Member perceptions of key quality indicators over time.

Introduction

Methodology: Patient Survey

- The Patient Survey was a web-based survey of adults (≥18 years old), United States residents who self-identified as "patients" with any medical condition and who could read, understand, and complete a web-based survey in the English language. The study recruited 582 people fitting this description.
- Potential participants were contacted by email using email addresses from the PMG Research, PLM (PatientsLikeMe), and CISCRP (Center for Information and Study on Clinical Research Participation) databases, as well as the AQC Membership. All contacts were made by the originating organizations; there was no transfer of email addresses or any other potentially identifying patient information to other organizations (including The Avoca Group), as part of this research, nor was any potentially identifying information gathered during the survey process.
- This minimal-risk research project was reviewed by WIRB and granted exempt status.

Introduction

Methodology: AQC Member Survey

- The AQC Member survey was a web-based survey of Sponsor and CRO Avoca Quality Consortium Members.
- A total of 188 respondents completed the survey, among key audiences as follows:
  - 103 from Sponsor organizations
  - 85 from CROs
- All surveys were completed between March and June of 2016.

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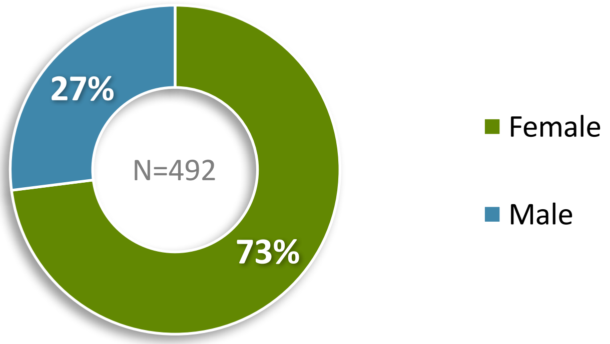
Characteristics of the Patient Sample

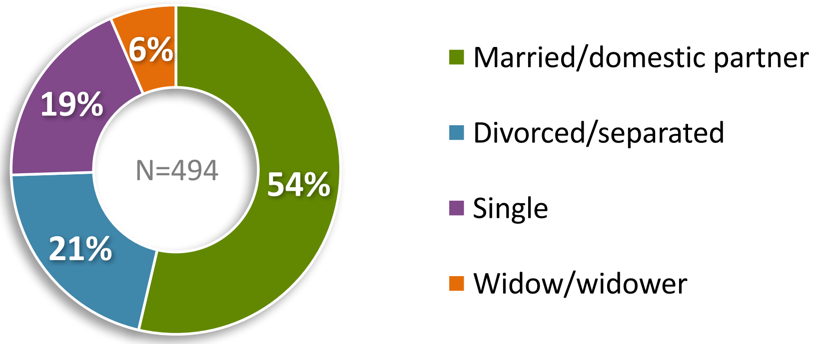
Characteristics of Patient Sample: Demographics

The sample was predominantly female, and 82% of participants were over age 45. Approximately half of respondents were living in marriages/domestic partnerships, and the vast majority (84%) resided in the Eastern or Midwestern US.

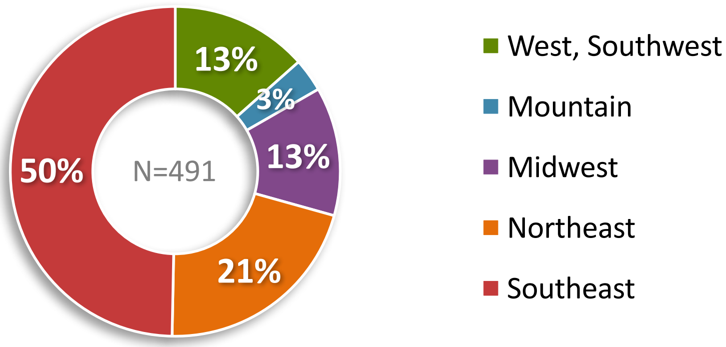
Sex



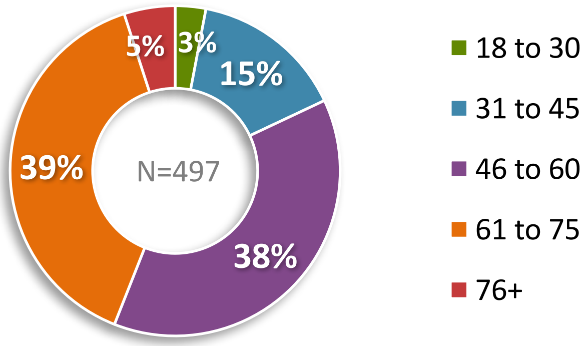
Marital Status



Region within the US



Age



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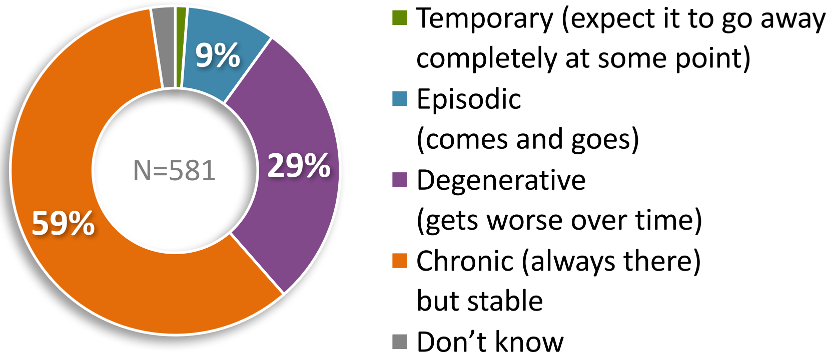
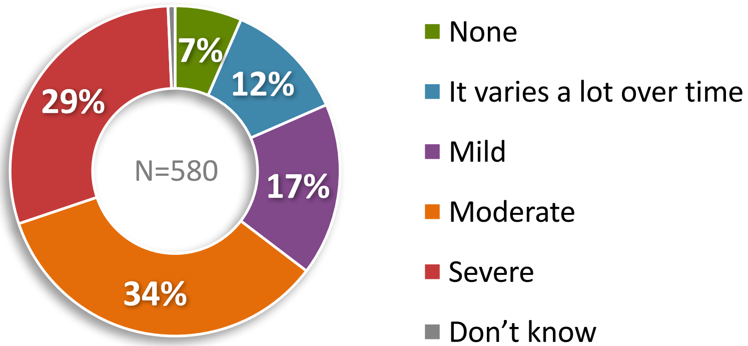
Characteristics of Patient Sample: Medical Conditions

The majority of respondents reported chronic or degenerative medical conditions, and most experienced moderate or severe impacts on their lives. About two-thirds saw their treating doctors between 2 and 12 times per year.

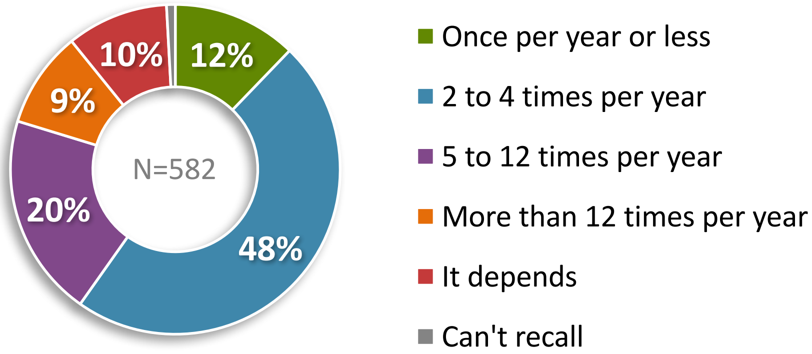
Type of Medical Condition



Impact of Medical Condition



How often do you see the doctor responsible for treating your condition?



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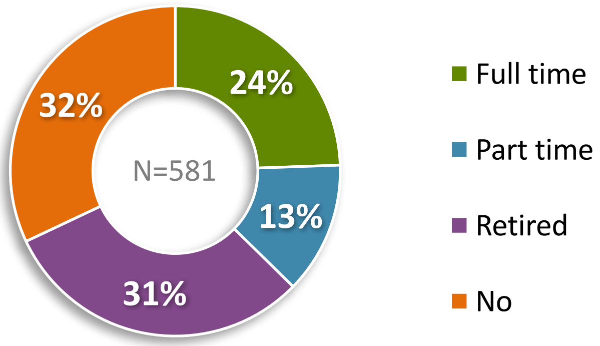
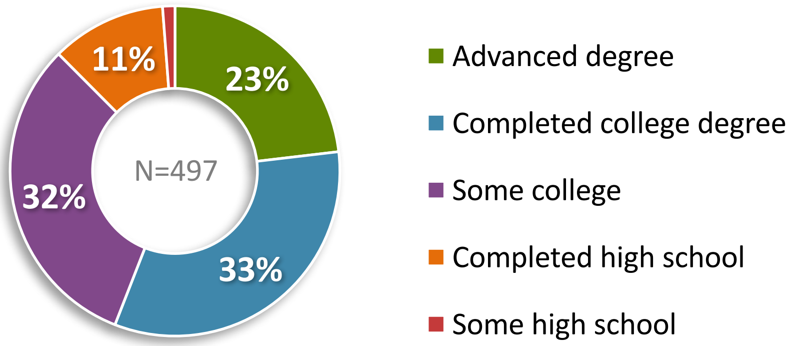
Characteristics of Patient Sample: Education and Employment

Respondents were largely well-educated, with more than half possessing a college degree. Approximately a third were employed, one-quarter full-time. Slightly under half were relied upon by family members for direct care or financial support.

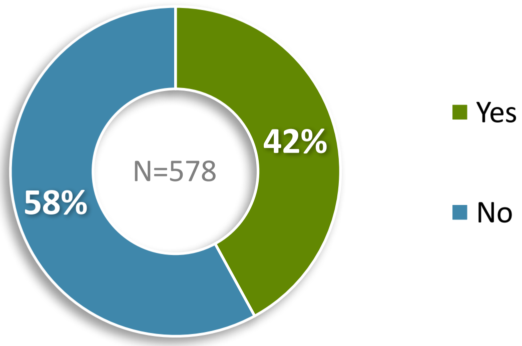
Are you currently employed?



Highest Level of Education



Do you have family members for whom you provide care or financial support?



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Characteristics of the AQC Member Sample

Characteristics of AQC Member Sample: Companies

Sponsors

103 respondents from
27 Member companies

# of respondents per company ranged from 1 to 11

- Alexion
- Alnylam
- Amgen
- Astellas
- Biogen
- Boehringer Ingelheim
- Bristol Myers Squibb
- CSL Behring
- Cidara
- Eli Lilly
- Endocyte
- GlaxoSmithKline
- Gilead Sciences
- Grünenthal
- Horizon
- Infinity
- Mitsubishi Tanabe Pharma
- Novartis
- Pfizer
- Pharmacyclics
- Purdue
- Raptor
- Roche
- Seattle Genetics
- Shire
- Sunovion
- Theravance

CROs

85 respondents from
6 Member companies

# of respondents per company ranged from 5 to 32

- Chiltern
- Covance
- ICON
- INC Research
- PPD
- PRA

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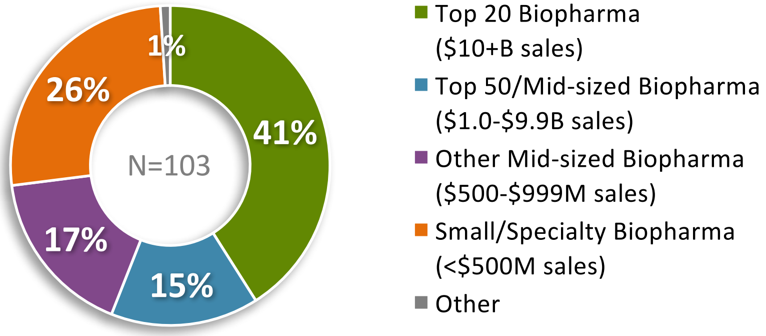
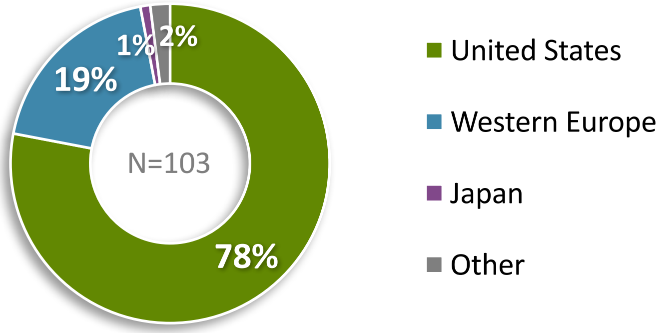
Characteristics of AQC Member Sample: Company Size & Location

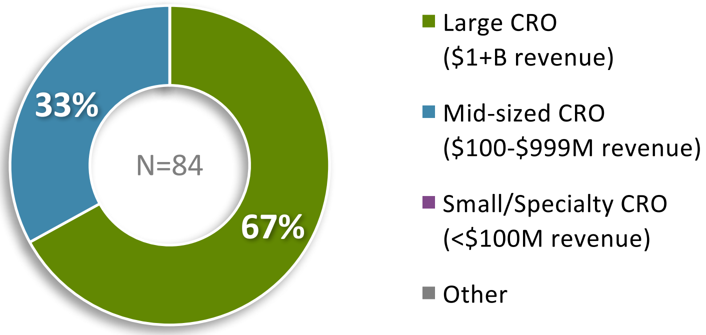
Sponsor respondents represented companies of varying size, while CRO respondents were comprised of Large and Mid-sized CROs. A majority of respondents from both Sponsors and CROs represented companies headquartered in the United States, with the remainder primarily in Western Europe.

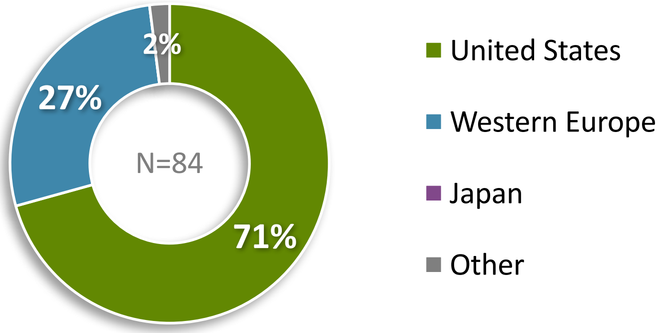
Sponsors





CROs

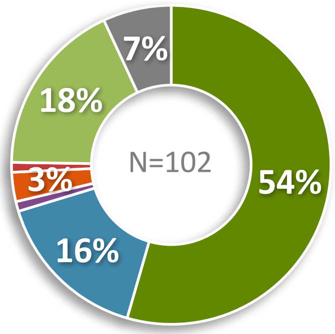




Characteristics of AQC Member Sample: Respondent Roles

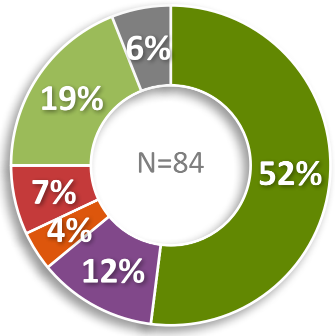
The sample was largely composed of respondents representing the Clinical Development/Operations function of their organizations, followed by Quality Assurance/Quality Control.

Sponsors



- 🟩 Clinical Development/Operations
- 🟦 Procurement/Outsourcing/ Vendor Management
- 🟪 Regulatory Affairs
- 🟧 Medical/Scientific
- 🟥 Executive Management
- 🟩 Quality Assurance/Quality Control
- ⬜ Other

CROs



- 🟩 Clinical Development/Operations
- 🟦 Business Development
- 🟪 Alliance Management/Partnerships
- 🟧 Medical/Scientific/Regulatory
- 🟥 Executive Management
- 🟩 Quality Assurance/Quality Control
- ⬜ Other

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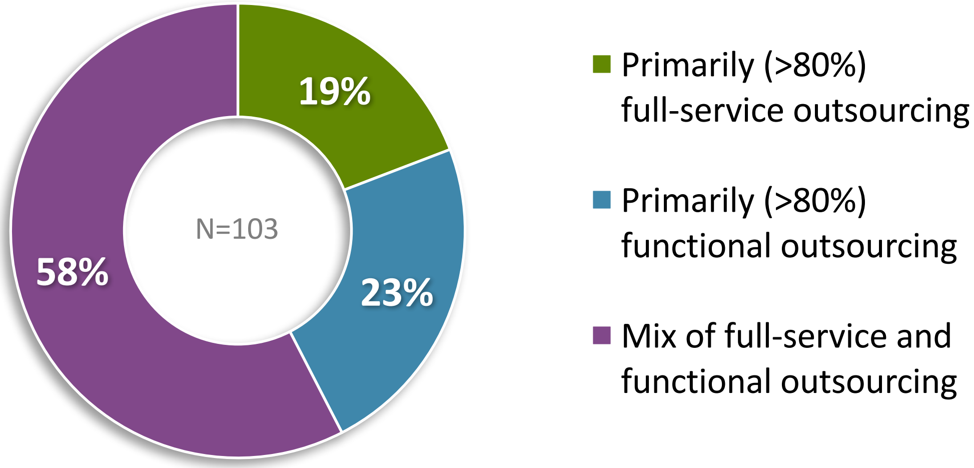
Characteristics of AQC Member Sample: Outsourcing Models

Approximately half of respondents from Sponsor organizations indicated that they utilize a mix of full-service and functional outsourcing for clinical development, followed by primarily using a functional provider and primarily utilizing a full-service approach.

Sponsors'
Outsourcing Models



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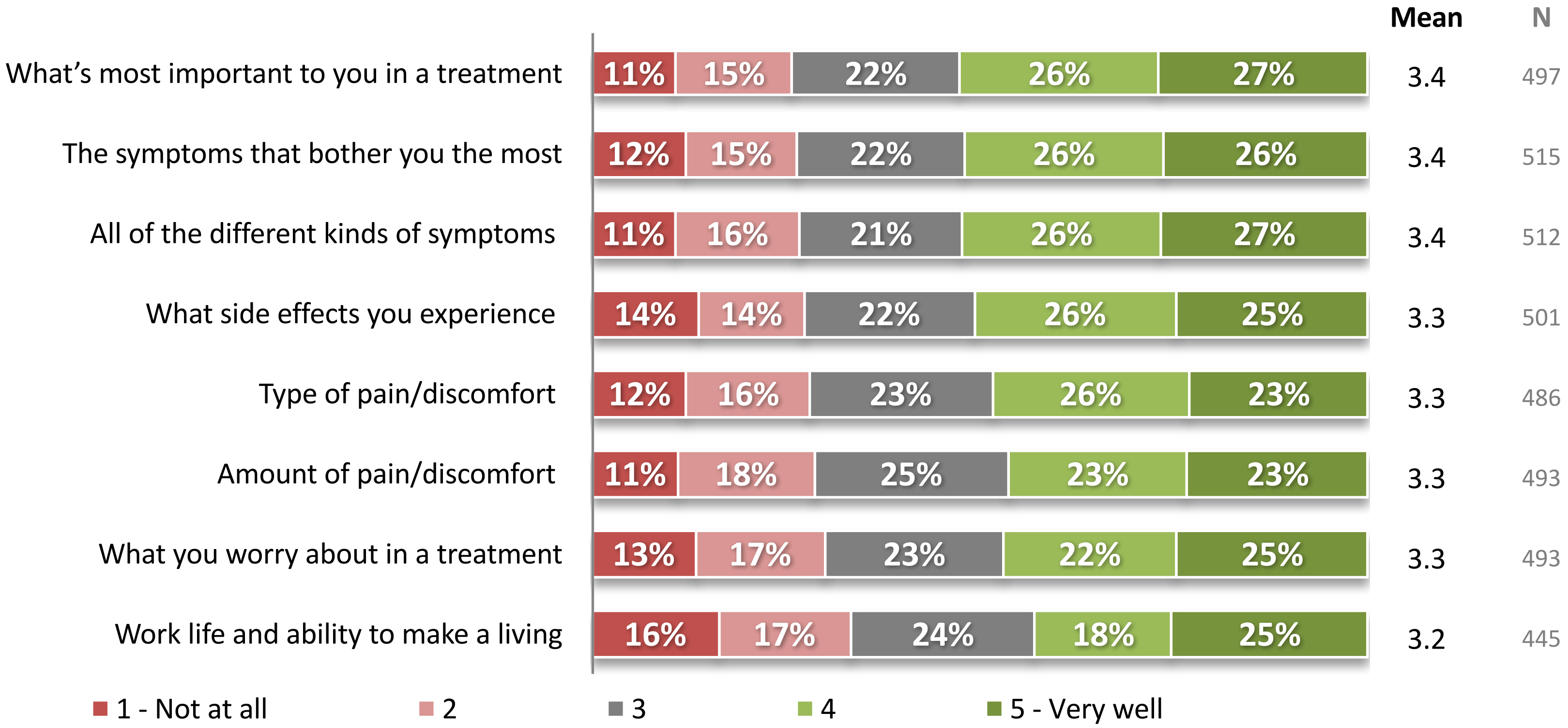
Patient Views on Understanding of their Conditions by Healthcare Providers

Patient Views on Understanding of their Conditions by Providers

On average, patients were not very impressed with their healthcare providers' understanding of what it's like to be a patient with their conditions. Means in this section of the survey ranged from 2.9 to 3.4 on a scale of 1 (understands not at all) to 5 (understands very well), and for each question, between 26% and 39% of patients gave a rating of 1 or 2.

How well do you believe that your doctor(s) and nurse(s) understand what it's like to be a patient with your condition, in each of the following ways?

Slide 1 of 2



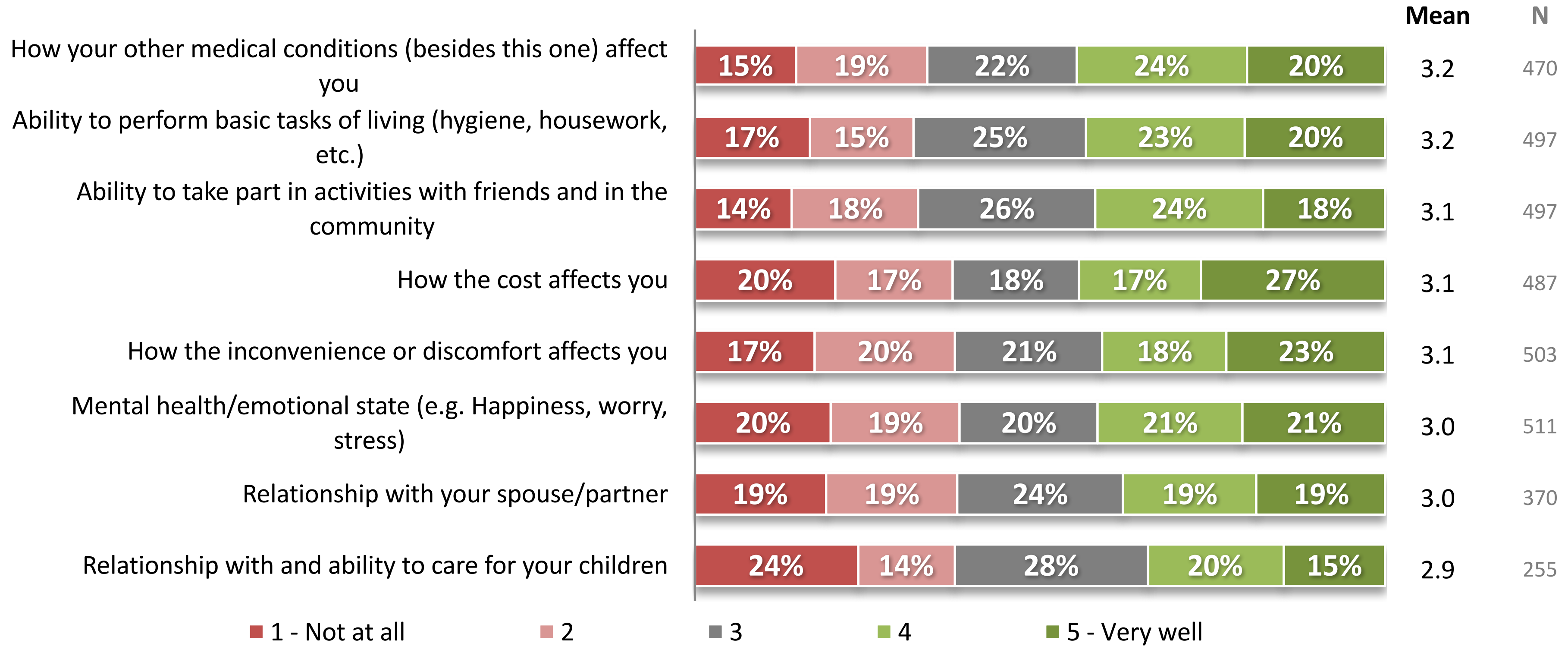
Scale of 1 (not at all) to 5 (very well). If you see more than one healthcare provider for your condition, and if your opinions regarding them are different, please respond for the healthcare provider who you see most often.

Patient Views on Understanding of their Conditions by Providers

Patients were on average most likely to feel that their providers understood their symptoms and treatment preferences, but were less likely to perceive that their providers understood the impacts of their conditions on their lives and particularly on their family relationships and ability to care for children.

How well do you believe that your doctor(s) and nurse(s) understand what it's like to be a patient with your condition, in each of the following ways?

Slide 2 of 2



Scale of 1 (not at all) to 5 (very well). If you see more than one healthcare provider for your condition, and if your opinions regarding them are different, please respond for the healthcare provider who you see most often.

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Patient Views on Understanding of their Conditions by Providers

Themes in Open-Ended Comments

- No-one can relate to pain/fatigue/symptoms like this, and their impacts, unless they have experienced it themselves
- Lack of “vocabulary” and/or self-tracking to appropriately convey experience to providers
- Providers are too busy to try to understand all of these things
  - Brief visits force patients to convey only “1 or 2 top symptoms;” focus on “ability to work for money” concerns at expense of “ability to play” or family concerns
- Not providers’ job to understand these things, not part of medicine
- Prescribing patterns do not take into account patient preferences re. trading a symptom for a side effect or risk; do not honor treatment refusals
- Doctors fail to track charts/histories, only grasp “what’s going on now”
- Specialist care means that each doctor only understands one part of the patient
- Patients purposefully don’t share this information (see later slides)
- Prescribing patterns (tests, treatments, referrals) demonstrate failure to understand logistics and stress of getting care, i.e. transportation concerns, financial concerns, insurance hassles, time off of work

Patient Views on Understanding by Providers: By Type of Condition

On average, patients with chronic conditions felt most understood by their providers. Those with degenerative conditions felt least understood when it came to most aspects of disease, but those with episodic conditions felt least understood with respect to impacts on their relationships and ability to function at work, at home, and in the community.

Perceptions of Doctors’ and Nurses’ Understanding of Patient Experience by Type of Medical Condition (only categories with N>10)

Mean ratings of perceived understanding on a scale of 1 (not at all) to 5 (very well)	**Chronic but stable**	**Degenerative**	**Episodic**
What’s most important to you in a treatment	3.6	3.2	3.3
The symptoms that bother you the most*	3.5	3.3	3.4
All of the different kinds of symptoms	3.5	3.2	3.4
What side effects you experience	3.4	3.2	3.5
Type of pain/discomfort *	3.4	3.1	3.2
Amount of pain/discomfort	3.4	3.2	3.3
What you worry about in a treatment	3.4	3.2	3.2
Work life and ability to make a living*	3.3	3.2	2.7
How your other medical conditions (besides this one) affect you	3.3	3.0	3.1
Ability to perform basic tasks of living (hygiene, housework, etc.)*	3.2	3.2	2.9
Ability to take part in activities with friends and in the community	3.2	3.2	2.9
How the cost affects you	3.2	3.1	3.2
How the inconvenience or discomfort affects you	3.1	3.0	3.2
Mental health/emotional state (e.g. Happiness, worry, stress)	3.1	3.1	3.1
Relationship with your spouse/partner	3.1	2.9	2.7
Relationship with and ability to care for your children*	3.0	3.0	2.3
N range=	149-299	70-152	25-47

Note: Highest mean per row highlighted in yellow, lowest in red; * p<.05 (unadjusted for multiple tests)

Patient Views on Understanding by Providers: By Impact of Condition

On average, patients with mild disease impacts felt most understood by their providers. Those at the extremes of the spectrum – with no impact or with severe impact – felt least understood when it came to most aspects of disease.

Perceptions of Doctors' and Nurses' Understanding of Patient Experience by Impact of Medical Condition

Mean ratings of perceived understanding on a scale of 1 (not at all) to 5 (very well)	Severe	Moderate	Mild	It varies	None
What's most important to you in a treatment	3.3	3.4	3.8	3.6	3.2
The symptoms that bother you the most**	3.2	3.4	3.8	3.5	3.2
All of the different kinds of symptoms**	3.2	3.4	3.9	3.3	3.3
What side effects you experience	3.3	3.3	3.6	3.3	3.2
Type of pain/discomfort	3.2	3.3	3.6	3.4	2.9
Amount of pain/discomfort*	3.1	3.3	3.7	3.3	3.0
What you worry about in a treatment	3.2	3.2	3.5	3.4	3.0
Work life and ability to make a living	3.3	3.1	3.2	3.0	2.8
How your other medical conditions (besides this one) affect you	3.0	3.2	3.4	3.1	3.2
Ability to perform basic tasks of living (hygiene, housework, etc.)	3.1	3.2	3.3	3.2	2.6
Ability to take part in activities with friends and in the community	3.2	3.1	3.2	3.1	2.7
How the cost affects you	3.1	3.0	3.4	3.2	3.2
How the inconvenience or discomfort affects you	3.0	3.0	3.4	3.1	3.0
Mental health/emotional state (e.g. Happiness, worry, stress)	3.0	3.0	3.2	3.1	2.7
Relationship with your spouse/partner	3.0	2.9	3.4	2.9	2.6
Relationship with and ability to care for your children	2.9	2.9	2.9	3.1	2.4
N range=	77-159	87-181	37-80	35-63	18-35

Note: Highest mean per row highlighted in yellow, lowest in red. * p<.05; ** p<.01 (unadjusted for multiple tests)

Patient Views on Understanding by Providers: By Frequency of Care

Patients with high "touch rates" with their doctors were no more likely to feel understood than were patients with less frequent contact.

Perceptions of Doctors' and Nurses' Understanding of Patient Experience by Frequency of Care

Mean ratings of perceived understanding on a scale of 1 (not at all) to 5 (very well)	**More than 12 times per year**	**5 to 12 times per year**	**2 to 4 times per year**	**Once per year or less**	**It depends**
What's most important to you in a treatment	3.1	3.4	3.5	3.4	3.5
The symptoms that bother you the most	3.4	3.2	3.5	3.4	3.4
All of the different kinds of symptoms*	3.4	3.1	3.6	3.5	3.3
What side effects you experience	3.2	3.3	3.5	3.1	3.4
Type of pain/discomfort	3.3	3.2	3.4	3.3	3.2
Amount of pain/discomfort	3.3	3.2	3.4	3.3	3.2
What you worry about in a treatment	3.1	3.3	3.4	3.0	3.5
Work life and ability to make a living	3.4	3.2	3.2	3.1	3.0
How your other medical conditions (besides this one) affect you	3.2	3.0	3.2	3.3	3.1
Ability to perform basic tasks of living (hygiene, housework, etc.)	3.0	3.1	3.2	3.3	3.0
Ability to take part in activities with friends and in the community	3.1	3.1	3.2	3.0	3.1
How the cost affects you	2.7	3.1	3.3	3.0	3.0
How the inconvenience or discomfort affects you	3.0	3.1	3.1	3.0	3.1
Mental health/emotional state (e.g. Happiness, worry, stress)	3.1	2.8	3.1	3.1	2.9
Relationship with your spouse/partner	3.0	2.9	3.1	2.8	2.8
Relationship with and ability to care for your children	2.9	2.9	2.9	2.8	2.8
N range=	34-53	52-104	116-251	25-60	27-53

Note: Highest mean per row highlighted in yellow, lowest in red. * p<.05; ** p<.01 (unadjusted for multiple tests)

Patient Views on Understanding by Providers: By Family Responsibility

Patients who were relied upon by family members for direct care and/or financial support were less likely than others to feel well-understood by their medical care providers, when it came to nearly every aspect of their conditions and lives.

Perceptions of Doctors' and Nurses' Understanding of Patient Experience by Family Responsibility

Mean ratings of perceived understanding on a scale of 1 (not at all) to 5 (very well)	**Yes (provides care or financial support to family members)**	**No**
What's most important to you in a treatment	3.4	3.5
The symptoms that bother you the most***	3.2	3.6
All of the different kinds of symptoms***	3.2	3.6
What side effects you experience	3.2	3.4
Type of pain/discomfort**	3.1	3.4
Amount of pain/discomfort**	3.1	3.4
What you worry about in a treatment	3.2	3.3
Work life and ability to make a living	3.2	3.2
How your other medical conditions (besides this one) affect you**	3.0	3.3
Ability to perform basic tasks of living (hygiene, housework, etc.)	3.1	3.2
Ability to take part in activities with friends and in the community	3.1	3.2
How the cost affects you	3.1	3.2
How the inconvenience or discomfort affects you	3.0	3.2
Mental health/emotional state (e.g. Happiness, worry, stress)	2.9	3.1
Relationship with your spouse/partner	3.0	3.0
Relationship with and ability to care for your children	2.8	2.9
N range=	144-217	110-297

Note: Highest mean per row highlighted in yellow, lowest in red. * p<.05; ** p<.01; ***p<.005 (unadjusted for multiple tests)

Patient Views on Understanding by Providers: By Employment Status

Employed patients were less likely than others to feel that the functional aspects of their conditions were well-understood by their providers. Those who worked full-time were least likely to feel that the cost, the inconvenience, and other worries about treatments were well-understood. Unemployed patients were least likely to feel that their pain/discomfort and other symptoms were well-understood.

Perceptions of Doctors' and Nurses' Understanding of Patient Experience by Current Employment

Mean ratings of perceived understanding on a scale of 1 (not at all) to 5 (very well)	**Full time**	**Part time**	**Retired**	**No**
What's most important to you in a treatment	3.4	3.6	3.5	3.4
The symptoms that bother you the most	3.4	3.4	3.5	3.3
All of the different kinds of symptoms	3.5	3.5	3.5	3.3
What side effects you experience	3.4	3.6	3.2	3.4
Type of pain/discomfort	3.3	3.5	3.4	3.2
Amount of pain/discomfort	3.4	3.3	3.4	3.1
What you worry about in a treatment	3.1	3.3	3.3	3.4
Work life and ability to make a living	3.0	3.0	3.2	3.4
How your other medical conditions (besides this one) affect you	3.4	3.1	3.2	3.0
Ability to perform basic tasks of living (hygiene, housework, etc.)	3.1	3.1	3.2	3.2
Ability to take part in activities with friends and in the community	3.0	3.0	3.2	3.2
How the cost affects you	3.0	3.2	3.2	3.2
How the inconvenience or discomfort affects you	3.0	3.1	3.2	3.1
Mental health/emotional state (e.g. Happiness, worry, stress)	3.0	2.9	3.0	3.2
Relationship with your spouse/partner	2.9	3.0	3.0	3.1
Relationship with and ability to care for your children	2.9	3.0	2.7	3.0
N range=	69-131	35-64	62-154	88-171

Note: Highest mean per row highlighted in yellow, lowest in red. * p<.05; ** p<.01 (unadjusted for multiple tests)

Patient Views on Understanding by Providers: By History of Trial Participation

Patients who had participated in clinical trials were more likely than others to feel well-understood by their medical care providers when it came to nearly every aspect of their conditions and lives, the only exceptions being the impacts of their conditions on family relationships.

Perceptions of Doctors' and Nurses' Understanding of Patient Experience by Have Ever Participated in a Clinical Trial

Mean ratings of perceived understanding on a scale of 1 (not at all) to 5 (very well)	**Yes**	**No**
What's most important to you in a treatment	3.6	3.3
The symptoms that bother you the most*	3.5	3.3
All of the different kinds of symptoms*	3.6	3.3
What side effects you experience*	3.5	3.2
Type of pain/discomfort	3.4	3.2
Amount of pain/discomfort*	3.4	3.2
What you worry about in a treatment	3.4	3.2
Work life and ability to make a living	3.3	3.1
How your other medical conditions (besides this one) affect you	3.2	3.1
Ability to perform basic tasks of living (hygiene, housework, etc.)	3.3	3.1
Ability to take part in activities with friends and in the community	3.2	3.1
How the cost affects you	3.2	3.1
How the inconvenience or discomfort affects you	3.2	3.0
Mental health/emotional state (e.g. Happiness, worry, stress)	3.1	3.0
Relationship with your spouse/partner	3.0	3.0
Relationship with and ability to care for your children	2.9	2.9
N range=	92-214	163-302

Note: Highest mean per row highlighted in yellow, lowest in red. * p<.05; ** p<.01 (unadjusted for multiple tests)

Patient Views on Understanding by Providers: By Age Group

Older patients were most likely to feel well-understood by their medical care providers when it came to nearly every aspect of their conditions, the exception being the side effects of treatments (the N for the 76+ age group was small, but the trend often extended to the 61-75 age group). Patients between ages 31-45 were least likely to feel understood. These trends may relate to those shown in previous slides regarding types of conditions experienced, employment status, family responsibilities, etc.

Perceptions of Doctors' and Nurses' Understanding of Patient Experience by Age

Mean ratings of perceived understanding on a scale of 1 (not at all) to 5 (very well)	76+	61-75	46-60	31-45	18-30
What's most important to you in a treatment	4.0	3.5	3.4	3.2	3.5
The symptoms that bother you the most**	4.0	3.6	3.4	2.9	3.4
All of the different kinds of symptoms***	3.9	3.6	3.4	2.9	3.6
What side effects you experience	3.5	3.4	3.4	3.1	3.8
Type of pain/discomfort*	3.8	3.5	3.2	2.9	3.5
Amount of pain/discomfort**	3.8	3.5	3.2	2.9	3.2
What you worry about in a treatment*	4.1	3.4	3.3	3.0	3.3
Work life and ability to make a living	3.8	3.2	3.3	2.9	2.9
How your other medical conditions (besides this one) affect you	3.3	3.3	3.2	3.0	2.9
Ability to perform basic tasks of living (hygiene, housework, etc.)**	3.5	3.3	3.2	2.6	3.2
Ability to take part in activities with friends and in the community*	3.3	3.3	3.1	2.7	3.1
How the cost affects you**	3.8	3.3	3.0	2.6	3.4
How the inconvenience or discomfort affects you	3.4	3.2	3.0	2.8	3.1
Mental health/emotional state (e.g. Happiness, worry, stress)	3.5	3.2	3.1	2.7	3.2
Relationship with your spouse/partner	3.5	3.1	3.0	2.6	3.2
Relationship with and ability to care for your children	4.0	2.9	2.9	2.5	3.7
N range=	5-18	78-185	96-183	44-71	6-14

Note: Highest mean per row highlighted in yellow, lowest in red. * p<.05; ** p<.01; ***p<.005 (unadjusted for multiple tests)

Patient Views on Understanding by Providers: By Sex

When it came to symptoms, particularly pain, females on average felt less understood by medical care providers than did males. This was also true for treatment preferences and for impacts on basic tasks of daily living and relationships, although the differences in these areas were smaller. Males felt slightly less understood than females when it came to impacts on work life and side effects.

Perceptions of Doctors' and Nurses' Understanding of Patient Experience by Sex

Mean ratings of perceived understanding on a scale of 1 (not at all) to 5 (very well)	**Female**	**Male**
What's most important to you in a treatment	3.4	3.6
The symptoms that bother you the most	3.4	3.6
All of the different kinds of symptoms*	3.3	3.6
What side effects you experience	3.4	3.3
Type of pain/discomfort	3.2	3.5
Amount of pain/discomfort	3.2	3.5
What you worry about in a treatment	3.3	3.3
Work life and ability to make a living	3.2	3.1
How your other medical conditions (besides this one) affect you	3.1	3.3
Ability to perform basic tasks of living (hygiene, housework, etc.)	3.1	3.2
Ability to take part in activities with friends and in the community	3.1	3.1
How the cost affects you	3.1	3.1
How the inconvenience or discomfort affects you	3.1	3.1
Mental health/emotional state (e.g. Happiness, worry, stress)	3.0	3.1
Relationship with your spouse/partner	2.9	3.0
Relationship with and ability to care for your children	2.8	2.9
N range=	167-340	59-121

Note: Highest mean per row highlighted in yellow, lowest in red. * p<.05; ** p<.01; ***p<.005 (unadjusted for multiple tests)

Patient Views on Understanding by Providers: By Marital Status

In general, patients who are single or married/partnered feel most understood by their medical care providers, whereas those who are divorced/separated, or particularly widowed, feel least understood. The differences across groups were again more pronounced for impacts on relationships than for the more clinical aspects of the condition.

Perceptions of Doctors' and Nurses' Understanding of Patient Experience by Marital Status

Mean ratings of perceived understanding on a scale of 1 (not at all) to 5 (very well)	**Married/ domestic partner**	**Divorced/ separated**	**Single**	**Widow/ widower**
What's most important to you in a treatment	3.5	3.3	3.6	3.3
The symptoms that bother you the most	3.5	3.3	3.5	3.0
All of the different kinds of symptoms	3.5	3.3	3.5	3.0
What side effects you experience	3.4	3.3	3.5	3.1
Type of pain/discomfort	3.4	3.1	3.5	3.1
Amount of pain/discomfort	3.4	3.1	3.4	3.0
What you worry about in a treatment	3.3	3.2	3.4	3.3
Work life and ability to make a living	3.2	3.0	3.3	3.4
How your other medical conditions (besides this one) affect you*	3.3	2.9	3.3	2.7
Ability to perform basic tasks of living (hygiene, housework, etc.)	3.2	3.1	3.3	2.8
Ability to take part in activities with friends and in the community	3.2	3.1	3.2	2.8
How the cost affects you	3.2	2.9	3.1	3.0
How the inconvenience or discomfort affects you	3.2	2.8	3.3	2.8
Mental health/emotional state (e.g. Happiness, worry, stress)	3.1	3.0	3.1	2.8
Relationship with your spouse/partner	3.1	2.8	3.0	2.3
Relationship with and ability to care for your children	2.8	2.9	3.1	2.1
N range=	129-249	49-101	36-86	8-31

Note: Highest mean per row highlighted in yellow, lowest in red. * p<.05; ** p<.01; ***p<.005 (unadjusted for multiple tests)

Patient Views on Understanding by Providers: By Educational Attainment

In general, there was a trend toward an inverse relationship between educational attainment and perceptions of understanding. This may reflect patterns of care received (i.e., rural one-doctor vs. urban multi-doctor, migration patterns over lifetime, etc.) and/or the trust placed in providers.

Perceptions of Doctors' and Nurses' Understanding of Patient Experience by Highest Level of Education (only categories with N>10)

Mean ratings of perceived understanding on a scale of 1 (not at all) to 5 (very well)	**Advanced degree**	**Completed college degree**	**Some college**	**Completed high school**
What's most important to you in a treatment	3.4	3.4	3.4	3.4
The symptoms that bother you the most	3.3	3.5	3.4	3.5
All of the different kinds of symptoms	3.4	3.6	3.4	3.2
What side effects you experience	3.4	3.3	3.3	3.5
Type of pain/discomfort	3.3	3.4	3.2	3.4
Amount of pain/discomfort	3.3	3.4	3.2	3.4
What you worry about in a treatment*	3.2	3.2	3.3	3.6
Work life and ability to make a living	3.1	3.3	3.1	3.3
How your other medical conditions (besides this one) affect you	3.1	3.3	3.1	3.3
Ability to perform basic tasks of living (hygiene, housework, etc.)	3.2	3.1	3.1	3.3
Ability to take part in activities with friends and in the community	3.0	3.0	3.2	3.3
How the cost affects you	3.1	3.0	3.2	3.1
How the inconvenience or discomfort affects you	2.9	3.1	3.1	3.2
Mental health/emotional state (e.g. Happiness, worry, stress)	2.9	3.1	3.0	3.2
Relationship with your spouse/partner	3.0	2.8	3.1	3.1
Relationship with and ability to care for your children	2.7	2.7	3.1	2.8
N range=	52-110	81-154	70-149	23-52

Note: Highest mean per row highlighted in yellow, lowest in red. * p<.05; ** p<.01; ***p<.005 (unadjusted for multiple tests)

Patient Views on Understanding by Providers: By Geographic Region

In general, patients residing in the Western US/Mountain areas felt less understood than did those in the Midwest or Eastern regions, except regarding the impacts of their conditions on their ability to work. Regional differences were particularly pronounced for impacts on relationships (both family and community), as opposed to clinical aspects of the disease such as symptoms/pain and ability to perform basic tasks of daily living, possibly reflecting cultural differences in communication.

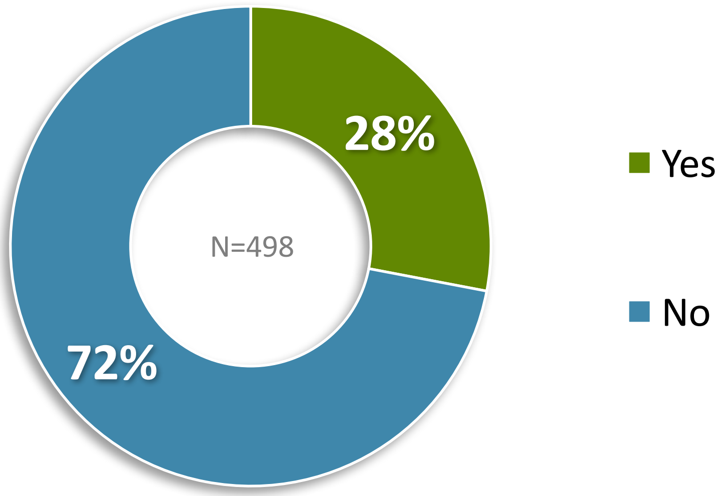
Perceptions of Doctors' and Nurses' Understanding of Patient Experience by Region

Mean ratings of perceived understanding on a scale of 1 (not at all) to 5 (very well)	West, Southwest	Mountain	Midwest	Northeast	Southeast
What's most important to you in a treatment	3.3	3.3	3.4	3.6	3.4
The symptoms that bother you the most	3.2	3.5	3.5	3.4	3.5
All of the different kinds of symptoms	3.2	3.2	3.4	3.5	3.5
What side effects you experience	3.2	2.8	3.5	3.4	3.4
Type of pain/discomfort	3.1	3.2	3.2	3.4	3.4
Amount of pain/discomfort	3.2	3.2	3.2	3.3	3.4
What you worry about in a treatment	3.1	3.1	3.4	3.3	3.3
Work life and ability to make a living	3.1	3.5	3.4	3.0	3.2
How your other medical conditions (besides this one) affect you	2.9	3.6	3.1	3.2	3.3
Ability to perform basic tasks of living (hygiene, housework, etc.)	3.0	3.0	3.2	3.2	3.2
Ability to take part in activities with friends and in the community	3.0	2.6	3.3	2.9	3.2
How the cost affects you	3.1	2.6	3.0	3.1	3.2
How the inconvenience or discomfort affects you	2.8	2.6	3.0	3.2	3.2
Mental health/emotional state (e.g. Happiness, worry, stress)	3.0	2.8	3.2	3.0	3.1
Relationship with your spouse/partner	2.9	2.5	3.2	2.7	3.1
Relationship with and ability to care for your children	2.7	2.2	3.0	2.8	2.9
N range=	36-63	5-16	33-62	51-95	100-227

Note: Highest mean per row highlighted in yellow, lowest in red. * p<.05; ** p<.01; ***p<.005 (unadjusted for multiple tests)

Understanding of Patients by Providers

Patients: Are there aspects of how your condition or treatment affects you that you do NOT share with your health care providers?



Understanding of Patients by Providers: Reasons for Not Sharing

- Embarrassment/shame in talking about e.g. disability, difficulty with personal or home care/hygiene, sexual or bowel dysfunction, etc.
- Concerns regarding confidentiality, not wanting it to become “part of record”
- Fear of e.g. getting driver’s license revoked, being prevented from working, being ushered into “psych track” of medical care
- Fear of being prescribed medications that they don’t want to take
- Fear of having currently prescribed medications “taken away”
- Emotionally difficult to talk about fears/anxieties, upsetting
- Fear of judgment regarding e.g. dietary habits/weight, sexual history/lifestyle, substance use, etc.
- Assumption that if healthcare providers don’t ask about these things, then they don’t care/not part of job; “medicine is about science, not about life”
- Fear of talking about something personal and meaningful and not being listened to; feeling unimportant, worthless
- Perception of being rushed through medical visits, no time to talk
- Previous experience with trying to talk to healthcare providers about these things and getting demeaning/uncaring responses → frustration and hurt
- Fear of losing services if they become labeled as “difficult,” “refractory,” “time-consuming,” or at risk for addiction

Understanding of Patients by Providers: Disease Aspects Not Shared

- Pain and psychological impacts thereof
- Disability, in work, self-care, care of others (e.g. children, pets)
- Emotional impacts of disease, i.e. anxiety, fears
  - *"I tried to tell him and he said he wasn't a social worker."*
- "Non-critical," "non-medical" aspects of disease, i.e. inability to "have fun," to perform particular self-care or child-care tasks, etc.
  - *"Some issues are not medical… I am having trouble buttoning my shirt. And, I can't bend over to tie shoes anymore. I can't reach my feet to put on socks."*
- Impacts on sexuality and relationships
- Implications of lifestyle decisions on disease, i.e. diet, sexual lifestyle, use of alternative therapies, etc.
- Any information that could impact privileges/permissions, i.e. visual effects that could impact driver's license, injuries/pain that could impact permission to return to work, cognitive issues that could impact independent living, etc.
- Bowel function
- Addiction/dependence
- Obesity-related issues
- Financial aspects of disease and/or treatment

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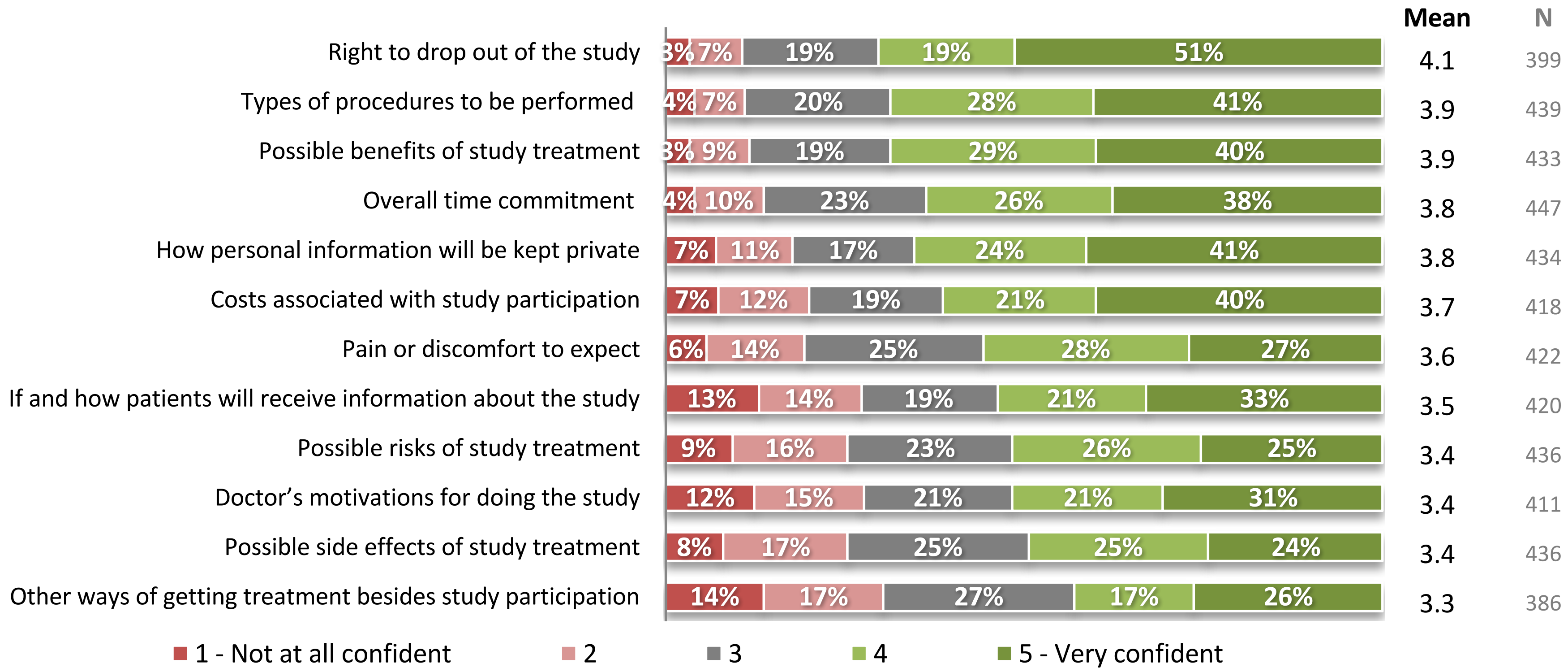
Confidence in Information Provided to Clinical Trial Participants

Patients’ Confidence in Clinical Trial Participant Information

Most patients had at least a fair level of confidence that trial participants are informed fully and honestly about the clinical trial process. Patients were most likely to be confident in information provided about right to withdraw, procedures, and possible benefits, and were most skeptical about information relating to treatment alternatives, risks and side effects, and doctors’ motivations.

When patients are approached about clinical trials run by pharmaceutical companies, how confident do you feel that they are informed fully and honestly about each of the following?



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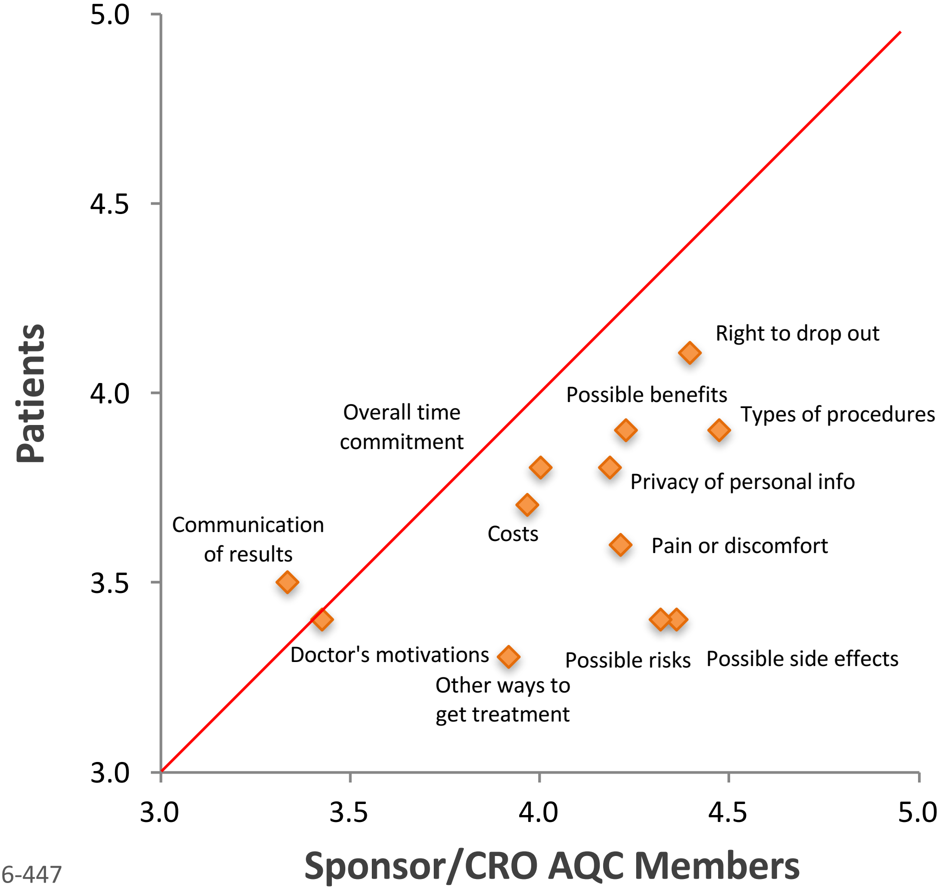
Patient vs. AQC Member Confidence in Clinical Trial Information

Both patients and AQC Member respondents were reasonably confident in patients' receipt of complete and honest information about the right to withdraw from a trial, its procedures, and its possible benefits, and both were skeptical about information regarding the communication of results and doctors' motivations. AQC Members were quite confident in patients' receipt of complete and honest information about possible side effects, risks, and discomforts, but patients were less so.

Confidence That Trial Participants are Informed About…

Mean Ratings: 1=Not At All Confident to 5=Very Confident



Patients: N=386-447

Sponsor N=83-94, CRO N=63-76 *Q: As a Sponsor/CRO executing trials on behalf of Sponsors, how confident are you that potential clinical trial participants are fully and honestly informed about each of the following?*

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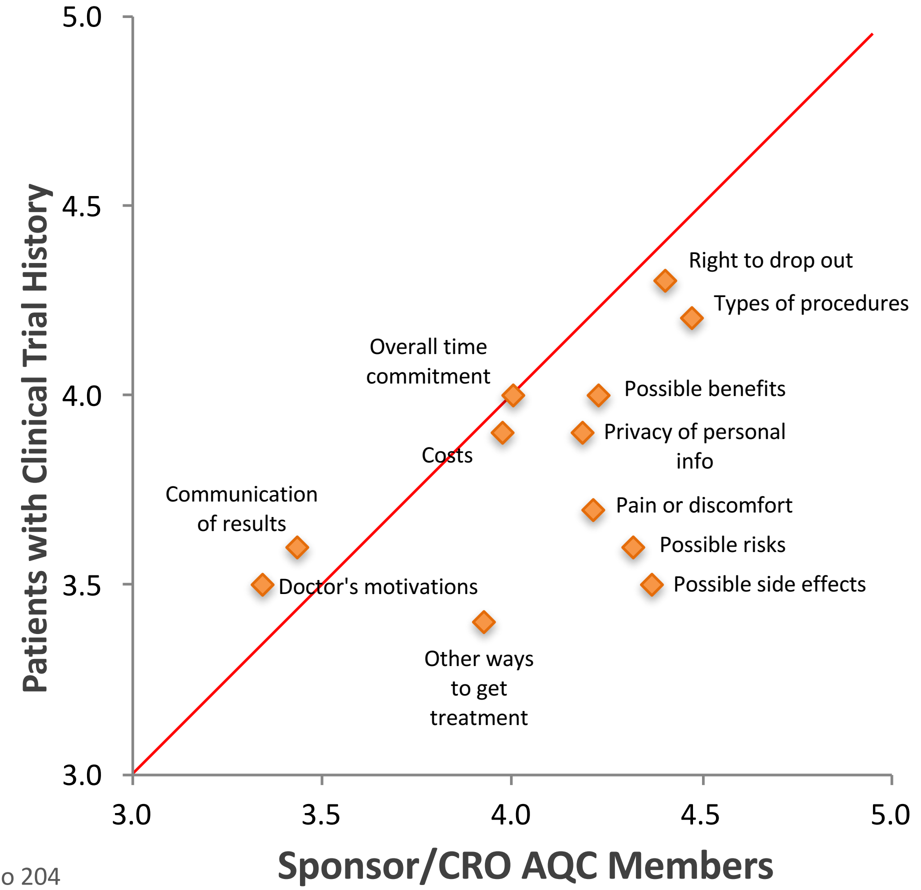
Patients with Clinical Trial History vs. AQC Member Confidence in Clinical Trial Information

Much of the patient-sponsor difference in confidence was driven by patients with no experience in clinical trials; patients with clinical trial experience had substantially greater levels of confidence – much closer to the levels exhibited by AQC members – than did those with no history of clinical trial participation (this slide and next).

Confidence That Trial Participants are Informed About…

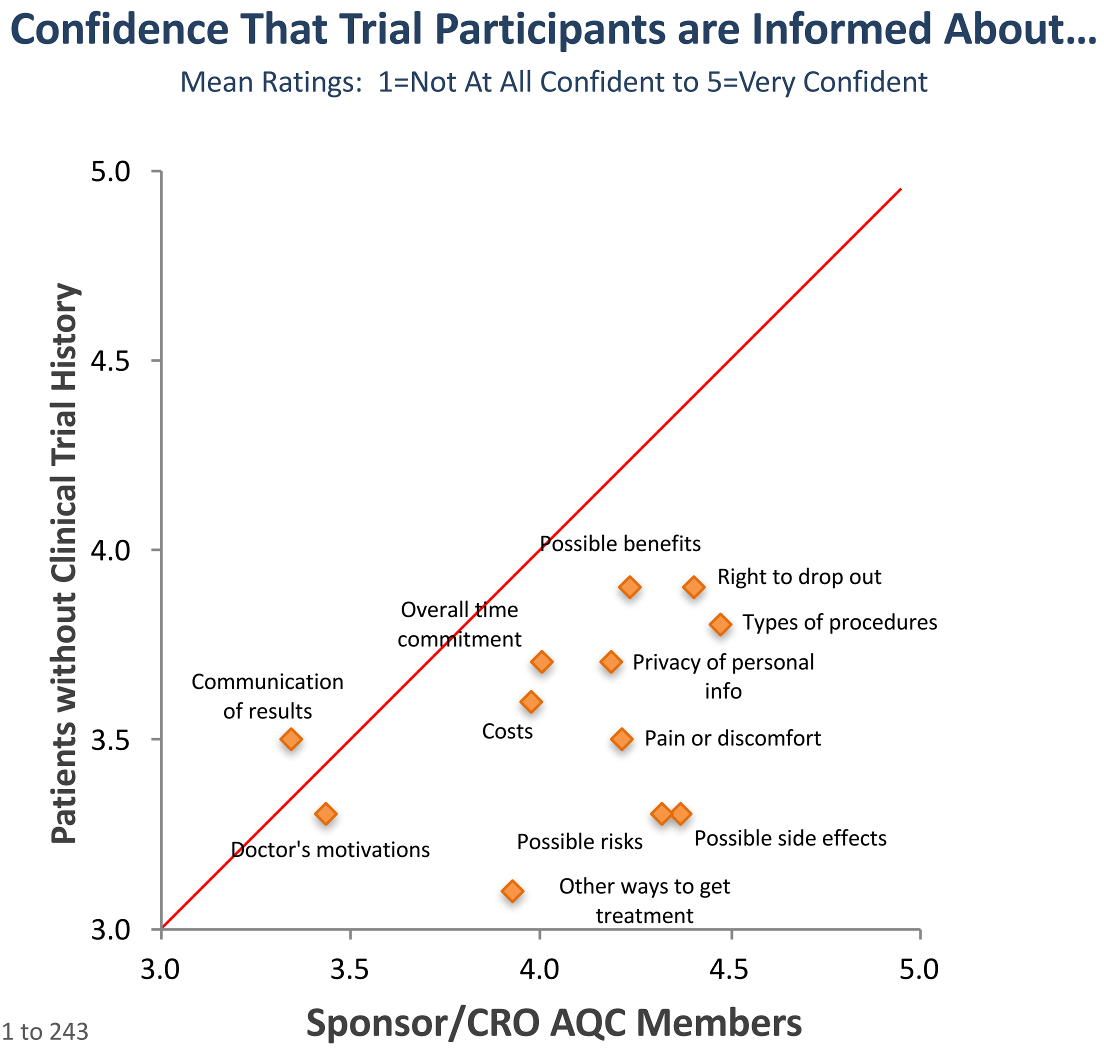
Mean Ratings: 1=Not At All Confident to 5=Very Confident



Patients: N=185 to 204

Sponsor N=83-94, CRO N=63-76 *Q: As a Sponsor/CRO executing trials on behalf of Sponsors, how confident are you that potential clinical trial participants are fully and honestly informed about each of the following?*

Patients without Clinical Trial History vs. AQC Member Confidence in Clinical Trial Information



Patients: N=201 to 243

Sponsor N=83-94, CRO N=63-76 *Q: As a Sponsor/CRO executing trials on behalf of Sponsors, how confident are you that potential clinical trial participants are fully and honestly informed about each of the following?*

Patients' Confidence in Clinical Trial Information: By Type of Condition

Patients with chronic conditions were on average more confident than others in the information provided to clinical trial participants, and those with episodic conditions were generally least confident.

Confidence that Study Patients are Fully and Honestly Informed by Type of Medical Condition (only categories with N>10)

Mean ratings on a scale of 1 (not at all confident) to 5 (very confident)	**Chronic but stable**	**Degenerative**	**Episodic**
Right to drop out of the study	4.1	4.0	3.9
Types of procedures to be performed	4.0	3.8	3.8
Possible benefits of study treatment	3.9	3.9	3.8
Overall time commitment	3.9	3.8	3.7
How personal information will be kept private	3.9	3.8	3.7
Costs associated with study participation	3.8	3.7	3.5
Pain or discomfort to expect*	3.7	3.4	3.6
If and how patients will receive information about the study, including their personal results*	3.6	3.4	2.9
Possible risks of study treatment	3.5	3.4	3.1
Doctor's motivations for doing the study	3.6	3.3	3.1
Possible side effects of study treatment*	3.5	3.3	3.1
Other ways of getting treatment besides study participation*	3.4	3.0	3.2
N range=	228-260	112-130	36-44

Note: Highest mean per row highlighted in yellow, lowest in red. * p<.05; ** p<.01; ***p<.005 (unadjusted for multiple tests)

Patients' Confidence in Clinical Trial Information: By Impact of Condition

Patients with mild conditions were on average more confident than others in the information provided to clinical trial participants.

Confidence that Study Patients are Fully and Honestly Informed by Impact of Medical Condition

Mean ratings on a scale of 1 (not at all confident) to 5 (very confident)	Severe	Moderate	Mild	It varies	None
Right to drop out of the study	4.1	4.0	4.3	4.3	3.8
Types of procedures to be performed	3.9	4.0	4.2	3.8	3.6
Possible benefits of study treatment	4.0	3.8	4.2	3.9	4.0
Overall time commitment	3.9	3.7	4.1	3.7	3.9
How personal information will be kept private*	3.8	3.6	4.3	3.8	3.7
Costs associated with study participation*	3.7	3.6	4.2	3.6	3.6
Pain or discomfort to expect	3.5	3.5	3.9	3.5	3.7
If and how patients will receive information about the study, including their personal results	3.4	3.4	3.7	3.4	3.6
Possible risks of study treatment*	3.3	3.3	3.9	3.3	3.6
Doctor's motivations for doing the study	3.4	3.3	3.7	3.3	3.8
Possible side effects of study treatment*	3.4	3.2	3.8	3.3	3.7
Other ways of getting treatment besides study participation***	3.0	3.1	3.9	3.5	3.5
N range=	113-135	142-156	64-75	42-56	22-29

Note: Highest mean per row highlighted in yellow, lowest in red. * p<.05; ** p<.01; ***p<.005 (unadjusted for multiple tests)

Patients' Confidence in Clinical Trial Information: By Frequency of Care

There was a general trend whereby patients who see their physicians frequently may be more skeptical about the information provided to clinical trial participants than were patients who see their physicians less often.

Confidence that Study Patients are Fully and Honestly Informed by Frequency of Care

Mean ratings on a scale of 1 (not at all confident) to 5 (very confident)	**More than 12 times per year**	**5 to 12 times per year**	**2 to 4 times per year**	**Once per year or less**	**It depends**
Right to drop out of the study	3.8	4.0	4.1	3.9	4.2
Types of procedures to be performed*	3.8	3.6	4.1	4.0	4.0
Possible benefits of study treatment	4.0	3.8	4.0	4.0	4.0
Overall time commitment	3.8	3.8	3.8	4.1	3.8
How personal information will be kept private	3.5	3.7	3.9	3.7	4.1
Costs associated with study participation	3.8	3.6	3.9	3.5	3.7
Pain or discomfort to expect*	3.6	3.2	3.6	3.9	3.7
If and how patients will receive information about the study, including their personal results	3.2	3.3	3.6	3.4	3.7
Possible risks of study treatment	3.4	3.1	3.5	3.5	3.7
Doctor's motivations for doing the study	3.4	3.4	3.5	3.4	3.6
Possible side effects of study treatment	3.4	3.1	3.5	3.5	3.5
Other ways of getting treatment besides study participation	3.1	3.0	3.3	3.5	3.4
N range=	37-43	70-83	191-224	43-49	37-48

Note: Highest mean per row highlighted in yellow, lowest in red. * p<.05; ** p<.01; ***p<.005 (unadjusted for multiple tests)

Patients' Confidence in Clinical Trial Information: By History of Trial Participation

Patients who had actually participated in clinical trials were more confident in the honesty and completeness of information provided to trial participants than were patients who had not, in every area except for one: how patients would receive study results, including personal results. Even among prior trial participants, however, confidence was not strong in some areas.

Confidence that Study Patients are Fully and Honestly Informed by History of Trial Participation

Mean ratings on a scale of 1 (not at all confident) to 5 (very confident)	**Yes**	**No**
Right to drop out of the study***	4.3	3.9
Types of procedures to be performed****	4.2	3.8
Possible benefits of study treatment	4.0	3.9
Overall time commitment**	4.0	3.7
How personal information will be kept private	3.9	3.7
Costs associated with study participation*	3.9	3.6
Pain or discomfort to expect	3.7	3.5
If and how patients will receive information about the study, including their personal results	3.5	3.5
Possible risks of study treatment**	3.6	3.3
Doctor's motivations for doing the study*	3.6	3.3
Possible side effects of study treatment*	3.5	3.3
Other ways of getting treatment besides study participation	3.4	3.1
N range=	185-204	201-243

Note: Highest mean per row highlighted in yellow, lowest in red. * p<.05; ** p<.01; ***p<.005; ****p=.0001 (unadjusted for multiple tests)

Patients' Confidence in Clinical Trial Information: By Age Group

In general, patients between 31 and 60 years of age were less confident in the honesty and completeness of information provided to trial participants than were younger or older patients.

Confidence that Study Patients are Fully and Honestly Informed by Age

Mean ratings on a scale of 1 (not at all confident) to 5 (very confident)	**76+**	**61-75**	**46-60**	**31-45**	**18-30**
Right to drop out of the study	4.2	4.2	4.0	3.9	4.1
Types of procedures to be performed	4.2	4.1	3.8	3.7	3.7
Possible benefits of study treatment	3.9	4.0	3.9	3.8	4.2
Overall time commitment	4.1	4.0	3.7	3.7	4.0
How personal information will be kept private	4.0	3.9	3.8	3.6	4.0
Costs associated with study participation*	4.3	4.0	3.5	3.5	3.9
Pain or discomfort to expect*	3.8	3.8	3.5	3.2	4.1
If and how patients will receive information about the study, including their personal results.	3.8	3.6	3.4	3.1	4.1
Possible risks of study treatment*	3.8	3.6	3.3	3.1	4.0
Doctor's motivations for doing the study	4.1	3.5	3.4	3.3	3.8
Possible side effects of study treatment*	3.7	3.6	3.3	3.2	3.6
Other ways of getting treatment besides study participation	3.7	3.4	3.3	2.8	2.9
N range=	13-19	156-180	150-171	52-65	9-10

Note: Highest mean per row highlighted in yellow, lowest in red. * p<.05; ** p<.01; ***p<.005 (unadjusted for multiple tests)

Patients' Confidence in Clinical Trial Information: By Educational Attainment

Particularly for the aspects of clinical trial information about which patients overall were less confident (toward the bottom of the table), there was generally an inverse relationship between educational attainment and confidence in the information provided.

Confidence that Study Patients are Fully and Honestly Informed by Highest Level of Education (only categories with N>10)

Mean ratings on a scale of 1 (not at all confident) to 5 (very confident)	**Advanced degree**	**Completed college degree**	**Some college**	**Completed high school**
Right to drop out of the study	4.2	3.9	4.0	4.4
Types of procedures to be performed	4.1	3.9	3.9	4.0
Possible benefits of study treatment	3.9	3.9	4.0	4.1
Overall time commitment	3.8	3.8	3.8	4.2
How personal information will be kept private	4.0	3.8	3.7	4.1
Costs associated with study participation	3.8	3.7	3.7	4.0
Pain or discomfort to expect	3.6	3.5	3.6	3.7
If and how patients will receive information about the study, including their personal results*	3.4	3.4	3.4	4.2
Possible risks of study treatment	3.4	3.3	3.5	3.5
Doctor's motivations for doing the study*	3.2	3.3	3.5	4.0
Possible side effects of study treatment	3.3	3.4	3.4	3.6
Other ways of getting treatment besides study participation	3.2	3.1	3.3	3.6
N range=	93-105	126-147	115-139	42-48

Note: Highest mean per row highlighted in yellow, lowest in red. * p<.05; ** p<.01; ***p<.005 (unadjusted for multiple tests)

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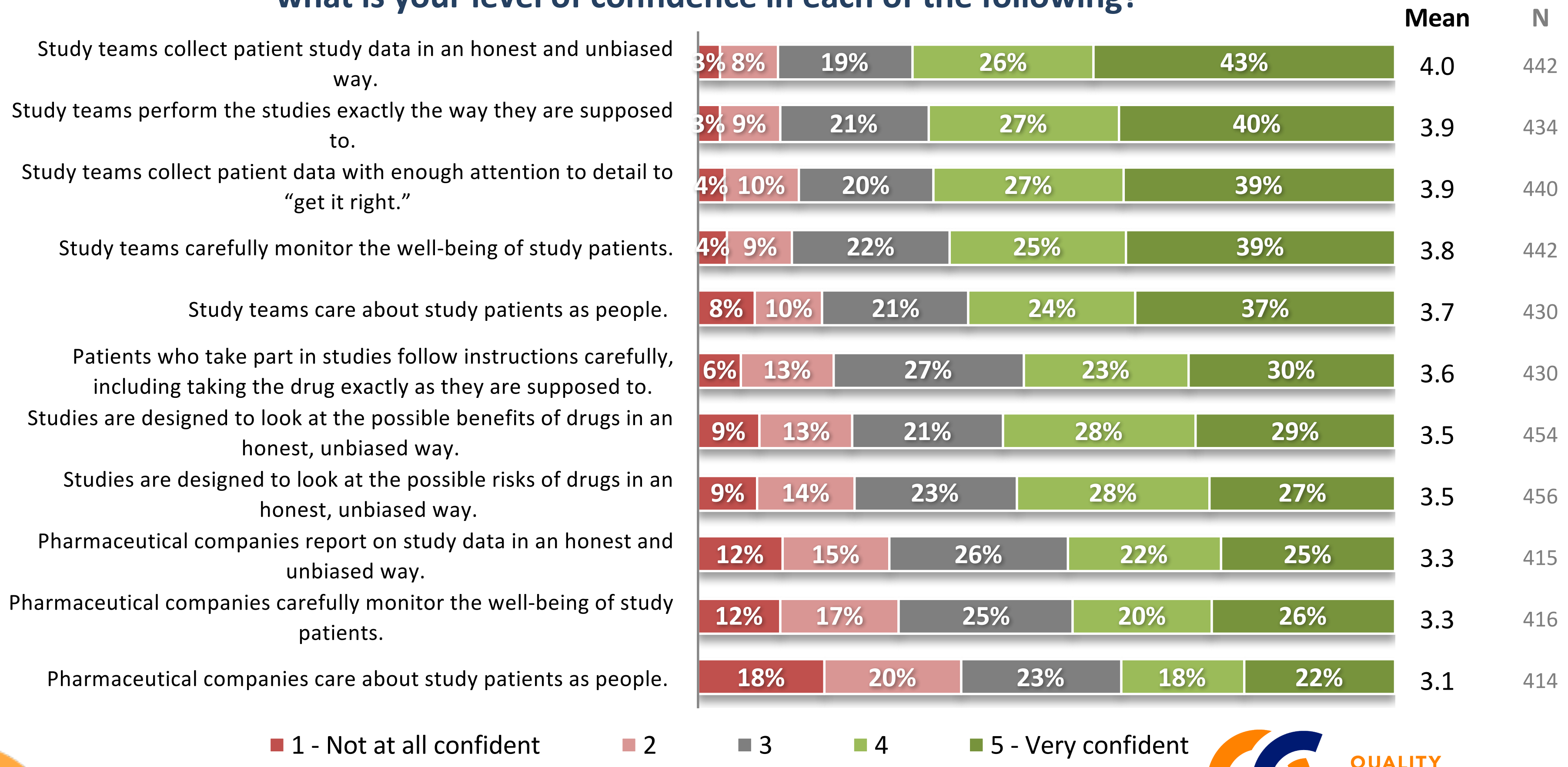
Confidence in Quality of Clinical Research Process

Patients’ Confidence in Clinical Trial Compliance and Ethics

Most patients had at least a fair level of confidence in the compliance, caring, and ethics of the site study teams and patients involved in clinical trials. However, many were skeptical about the honesty of pharmaceutical companies and about the extent to which they cared about study patients.

When it comes to clinical trials run by pharmaceutical companies, what is your level of confidence in each of the following?



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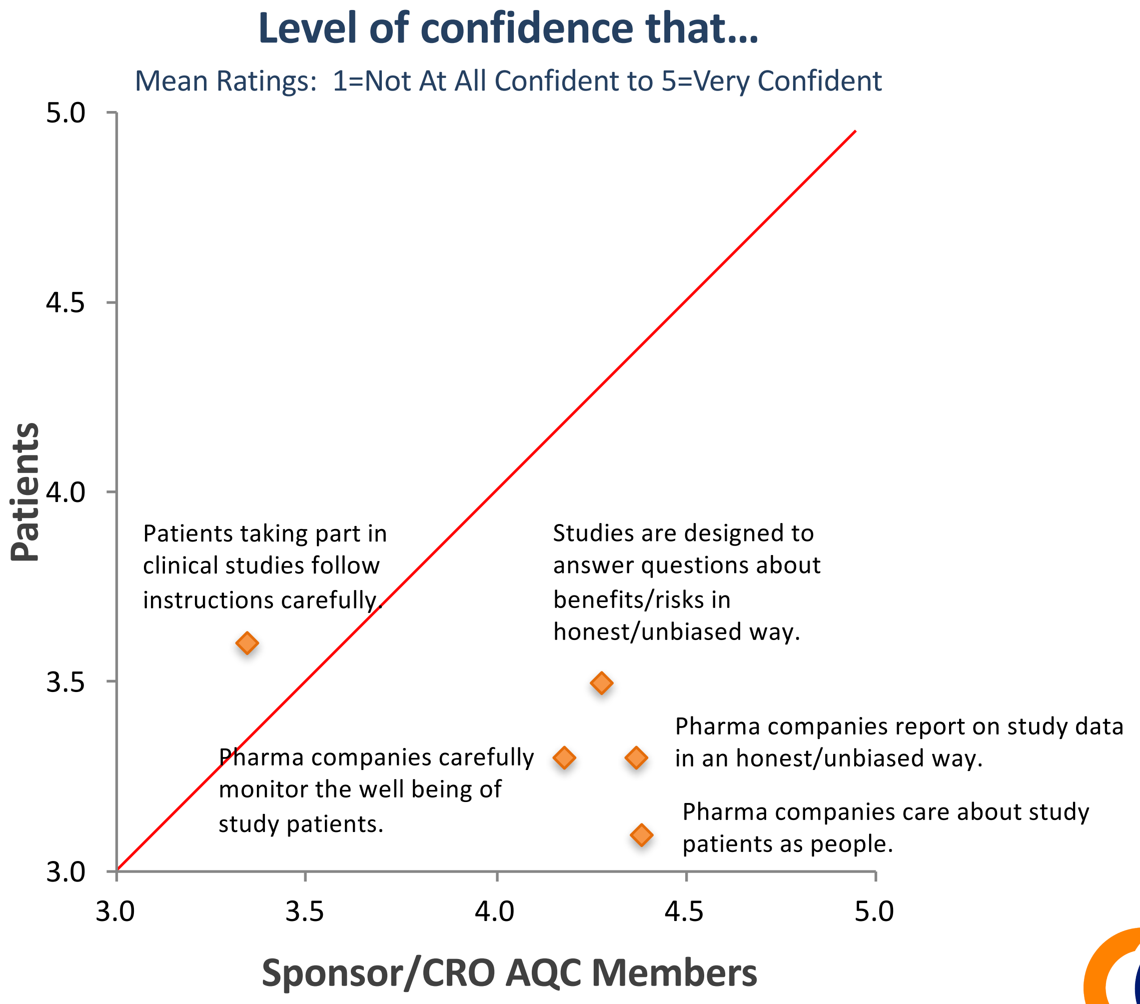
Patient vs. AQC Member Confidence in Sponsors’ and Patients’ Clinical Trial Compliance and Ethics

On average, both patients and AQC Member respondents were slightly skeptical about the compliance of patients taking part in clinical studies. However, patients were much more skeptical about the honesty and caring of pharmaceutical companies than were AQC Members.

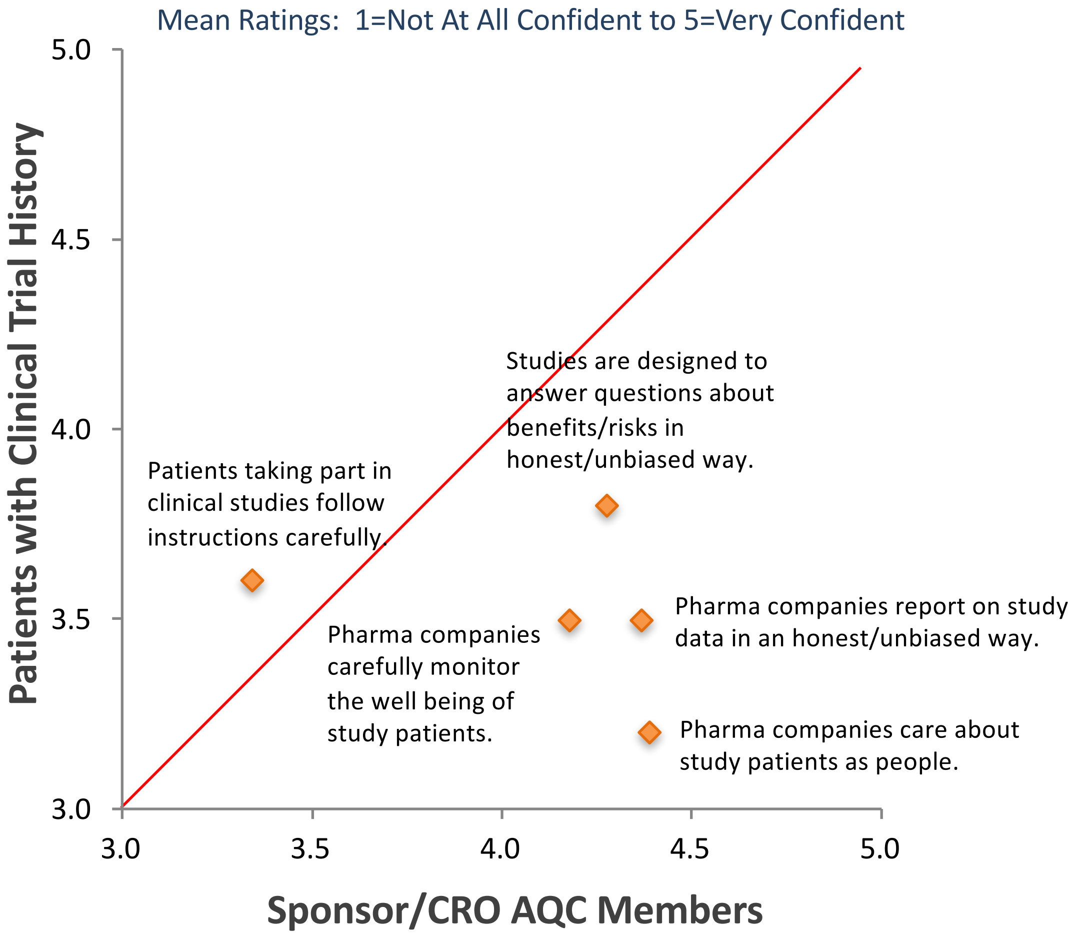


Sponsor N=95-99, CRO N=75-83; Patients N=414-456

Patient vs. AQC Member Confidence in Sponsors' and Patients' Clinical Trial Compliance and Ethics

Again, much of the patient-sponsor difference in confidence was driven by patients with no experience in clinical trials; patients with clinical trial experience had substantially greater levels of confidence – much closer to the levels exhibited by AQC members – than did those with no history of clinical trial participation (this slide and next).

Level of confidence that…

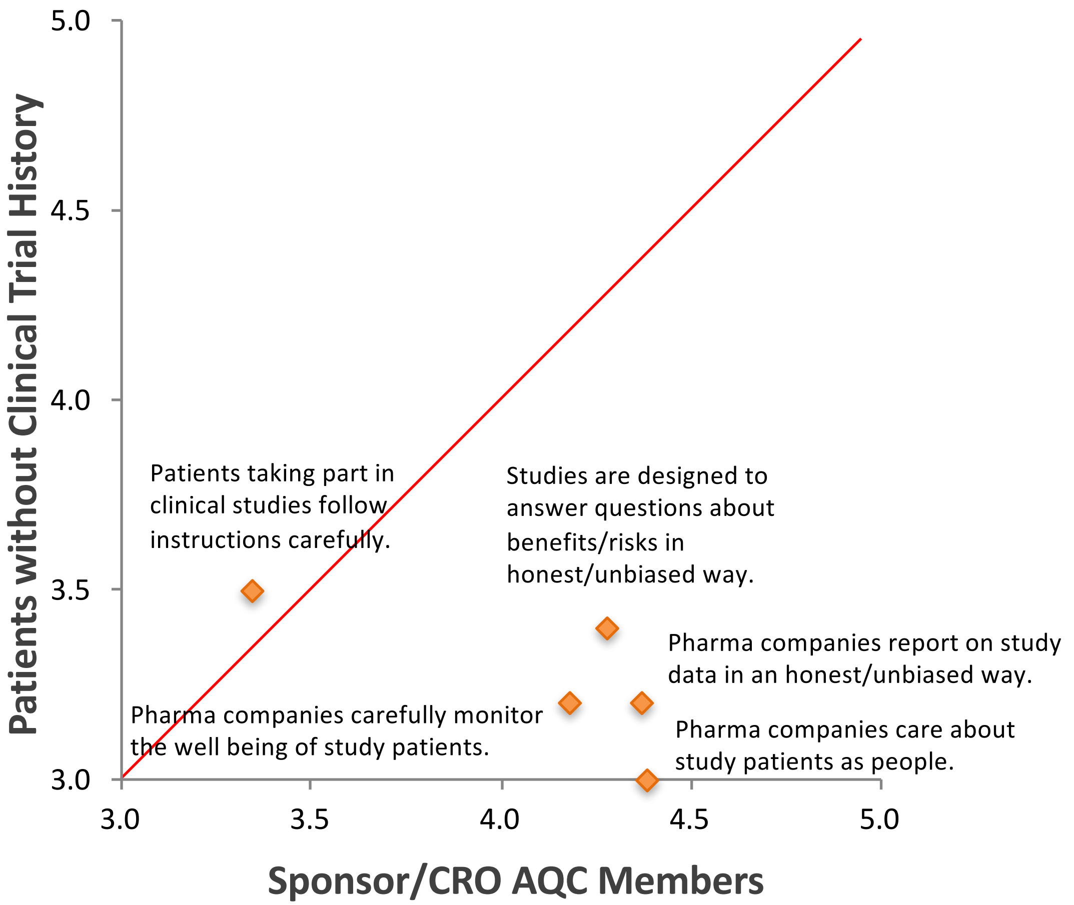


Sponsor N=95-99, CRO N=75-83; Patients N=178-201

Patients with No Clinical Trial History vs. AQC Member Confidence in Sponsors' and Patients' Clinical Trial Compliance and Ethics

Level of confidence that…

Mean Ratings: 1=Not At All Confident to 5=Very Confident



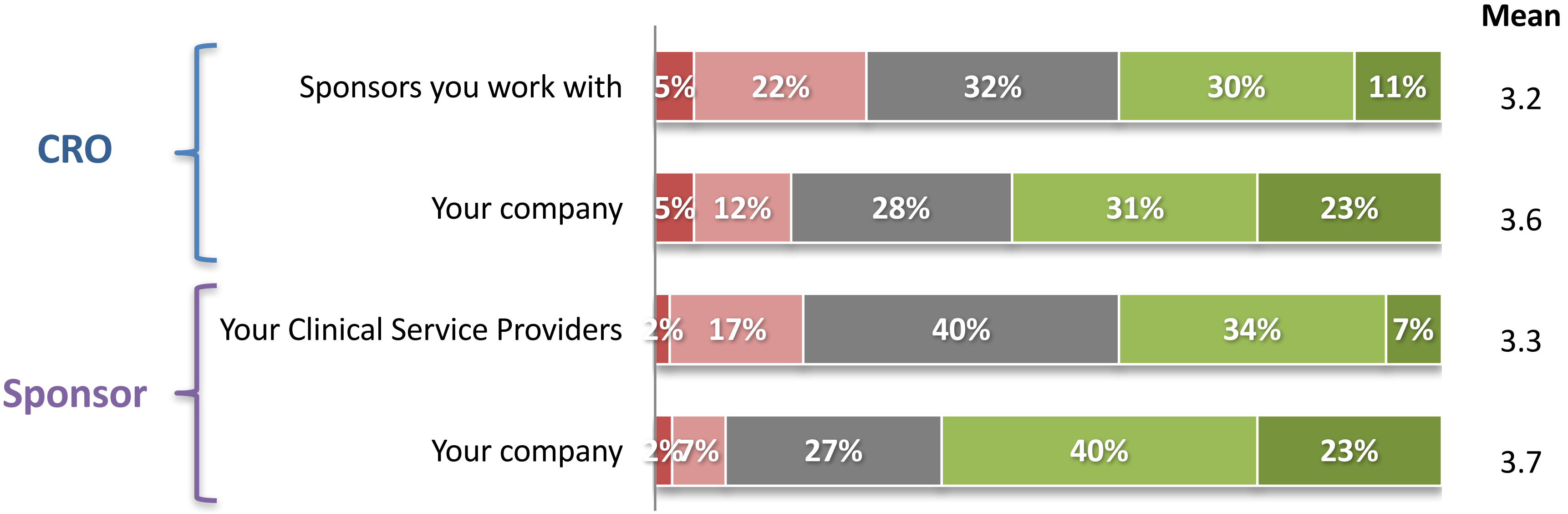
Sponsor N=95-99, CRO N=75-83; Patients N=230-258

AQC Members: Perceptions of Patient-Centric Thinking

When asked how well patient-centric thinking is incorporated into the design and execution of clinical trials, both Sponsors and CROs rate themselves similarly, more or less in the neutral range. However, both groups rate their partners lower and towards a more neutral position than they see themselves.

Perceptions of Patient Centricity in Trial Design & Execution

Mean Ratings: 1=Not Well At All to 5=Very Well



Sponsor N=88-95, CRO N=76-81

Q: Please rate your company and your Clinical Service Providers/Sponsors you have worked with in the past year on how well patient-centric thinking is incorporated into the design and execution of clinical trials.

Patients’ Confidence in Trial Compliance/Ethics: By Type of Condition

Patients with chronic conditions were on average more confident than others in the compliance, ethics, and caring of those executing clinical trials, and those with degenerative conditions were generally least confident.

Confidence in Clinical Trial Compliance and Ethics by Type of Medical Condition

(only categories with N>10)

Mean ratings on a scale of 1 (not at all confident) to 5 (very confident)	**Chronic**	**Degenerative**	**Episodic**
Study teams collect patient study data in an honest and unbiased way.	4.0	3.9	3.9
Study teams perform the studies exactly the way they are supposed to.	4.0	3.8	3.8
Study teams collect patient data with enough attention to detail to “get it right.”	3.9	3.8	3.8
Study teams carefully monitor the well-being of study patients.	3.9	3.7	3.9
Study teams care about study patients as people.	3.8	3.6	3.6
Patients who take part in studies follow instructions carefully, including taking the drug exactly as they are supposed to.	3.6	3.5	3.6
Studies are designed to look at the possible benefits of drugs in an honest, unbiased way.	3.6	3.4	3.5
Studies are designed to look at the possible risks of drugs in an honest, unbiased way. **	3.6	3.3	3.3
Pharmaceutical companies report on study data in an honest and unbiased way.	3.4	3.1	3.4
Pharmaceutical companies carefully monitor the well-being of study patients.	3.4	3.1	3.6
Pharmaceutical companies care about study patients as people.	3.2	2.8	3.0
N range=	232-263	123-141	38-41

Note: Highest mean per row highlighted in yellow, lowest in red. * p<.05; ** p<.01; ***p<.005 (unadjusted for multiple tests)

Patients’ Confidence in Trial Compliance/Ethics: By Impact of Condition

On average, patients with mild disease were more confident than others in the compliance, ethics, and caring of those executing clinical trials, and those with moderate or variable severity were generally least confident.

Confidence in Clinical Trial Compliance and Ethics by Impact of Medical Condition

Mean ratings on a scale of 1 (not at all confident) to 5 (very confident)	Severe	Moderate	Mild	It varies	None
Study teams collect patient study data in an honest and unbiased way.	4.0	3.9	4.2	3.9	4.0
Study teams perform the studies exactly the way they are supposed to.	4.0	3.8	4.2	3.9	4.0
Study teams collect patient data with enough attention to detail to “get it right.”	3.9	3.8	4.1	3.8	3.9
Study teams carefully monitor the well-being of study patients.	3.8	3.7	4.1	3.8	4.0
Study teams care about study patients as people.	3.7	3.6	4.1	3.6	3.9
Patients who take part in studies follow instructions carefully, including taking the drug exactly as they are supposed to.	3.6	3.5	3.6	3.6	3.8
Studies are designed to look at the possible benefits of drugs in an honest, unbiased way.	3.5	3.4	3.9	3.4	3.6
Studies are designed to look at the possible risks of drugs in an honest, unbiased way.	3.5	3.4	3.8	3.3	3.8
Pharmaceutical companies report on study data in an honest and unbiased way.	3.3	3.2	3.8	3.2	3.4
Pharmaceutical companies carefully monitor the well-being of study patients. *	3.2	3.2	3.8	3.2	3.5
Pharmaceutical companies care about study patients as people.	3.0	2.9	3.5	3.0	3.2
N range=	124-139	144-159	60-72	53-59	25-29

Note: Highest mean per row highlighted in yellow, lowest in red. * p<.05; ** p<.01; ***p<.005 (unadjusted for multiple tests)

Patients' Confidence in Trial Compliance/Ethics: By Frequency of Care

On average, patients who saw their treating physicians frequently were more skeptical about the compliance, ethics, and caring of those executing clinical trials than were those who saw their providers less frequently.

Confidence in Clinical Trial Compliance and Ethics by Frequency of Care

Mean ratings on a scale of 1 (not at all confident) to 5 (very confident)	More than 12 times per year	5 to 12 times per year	2 to 4 times per year	Once per year or less	It depends
Study teams collect patient study data in an honest and unbiased way.	3.9	3.8	4.0	4.1	4.0
Study teams perform the studies exactly the way they are supposed to.	3.9	3.7	4.0	4.1	4.0
Study teams collect patient data with enough attention to detail to "get it right."	3.6	3.7	4.0	3.9	3.9
Study teams carefully monitor the well-being of study patients.	3.8	3.6	3.9	3.9	4.1
Study teams care about study patients as people.	3.5	3.4	3.8	3.9	3.9
Patients who take part in studies follow instructions carefully, including taking the drug exactly as they are supposed to.	3.4	3.6	3.6	3.6	3.5
Studies are designed to look at the possible benefits of drugs in an honest, unbiased way.	3.3	3.3	3.6	3.6	3.7
Studies are designed to look at the possible risks of drugs in an honest, unbiased way.	3.5	3.4	3.5	3.6	3.5
Pharmaceutical companies report on study data in an honest and unbiased way.	3.2	3.0	3.4	3.5	3.3
Pharmaceutical companies carefully monitor the well-being of study patients.	3.1	3.2	3.4	3.5	3.3
Pharmaceutical companies care about study patients as people.	2.9	2.9	3.1	3.2	3.1
N range=	38-43	78-88	202-224	43-51	42-49

Note: Highest mean per row highlighted in yellow, lowest in red. * p<.05; ** p<.01; ***p<.005 (unadjusted for multiple tests)

Patients' Confidence in Trial Compliance/Ethics: By History of Trial Participation

On average, patients who had participated in clinical trials were more confident in the compliance, ethics, and caring of those executing clinical trials than were those who had not.

Confidence in Clinical Trial Compliance and Ethics by History of Trial Participation

Mean ratings on a scale of 1 (not at all confident) to 5 (very confident)	**Yes**	**No**
Study teams collect patient study data in an honest and unbiased way. ***	4.2	3.8
Study teams perform the studies exactly the way they are supposed to. *	4.1	3.8
Study teams collect patient data with enough attention to detail to "get it right."****	4.1	3.7
Study teams carefully monitor the well-being of study patients. ***	4.1	3.7
Study teams care about study patients as people. ***	4.0	3.5
Patients who take part in studies follow instructions carefully, including taking the drug exactly as they are supposed to.	3.6	3.5
Studies are designed to look at the possible benefits of drugs in an honest, unbiased way. ***	3.8	3.4
Studies are designed to look at the possible risks of drugs in an honest, unbiased way. **	3.7	3.4
Pharmaceutical companies report on study data in an honest and unbiased way. **	3.5	3.2
Pharmaceutical companies carefully monitor the well-being of study patients.	3.5	3.2
Pharmaceutical companies care about study patients as people.	3.2	3.0
N range=	178-201	230-258

Note: Highest mean per row highlighted in yellow, lowest in red. * p<.05; ** p<.01; ***p<.005 ; ****p<.0001 (unadjusted for multiple tests)

Patients’ Confidence in Trial Compliance/Ethics: By Educational Attainment

In general, there was an inverse relationship between level of educational attainment and confidence in the compliance, ethics, and caring of those executing clinical trials.

Confidence in Clinical Trial Compliance and Ethics by Highest Level of Education

(categories with N>10 only)

Mean ratings on a scale of 1 (not at all confident) to 5 (very confident)	**Advanced degree**	**Completed college degree**	**Some college**	**Completed high school**
Study teams collect patient study data in an honest and unbiased way.*	3.8	4.0	4.0	4.3
Study teams perform the studies exactly the way they are supposed to.**	3.7	3.9	3.9	4.3
Study teams collect patient data with enough attention to detail to “get it right.” *	3.7	3.8	3.9	4.3
Study teams carefully monitor the well-being of study patients.	3.7	3.9	3.9	4.1
Study teams care about study patients as people.	3.4	3.8	3.8	4.0
Patients who take part in studies follow instructions carefully, including taking the drug exactly as they are supposed to. *	3.3	3.5	3.7	3.7
Studies are designed to look at the possible benefits of drugs in an honest, unbiased way.	3.3	3.6	3.6	3.8
Studies are designed to look at the possible risks of drugs in an honest, unbiased way.	3.3	3.6	3.4	3.8
Pharmaceutical companies report on study data in an honest and unbiased way. **	2.9	3.4	3.4	3.7
Pharmaceutical companies carefully monitor the well-being of study patients. *	3.0	3.4	3.3	3.7
Pharmaceutical companies care about study patients as people. **	2.7	3.1	3.1	3.5
N range=	100-109	129-144	131-149	40-48

Note: Highest mean per row highlighted in yellow, lowest in red. * p<.05; ** p<.01; ***p<.005 ; ****p<.0001 (unadjusted for multiple tests)

Patients' Confidence in Trial Compliance/Ethics: By Age Group

In general, patients between 31 and 60 years of age were less confident in the compliance, ethics, and caring of those involved in clinical trial execution than were younger or older patients. Those in the 76+ age group had the highest level of confidence.

Confidence in Clinical Trial Compliance and Ethics by Age

Mean ratings on a scale of 1 (not at all confident) to 5 (very confident)	**76+**	**61-75**	**46-60**	**31-45**	**18-30**
Study teams collect patient study data in an honest and unbiased way. *	4.5	4.1	3.9	3.7	3.9
Study teams perform the studies exactly the way they are supposed to. **	4.6	4.1	3.8	3.7	4.0
Study teams collect patient data with enough attention to detail to "get it right."	4.3	4.0	3.8	3.6	4.0
Study teams carefully monitor the well-being of study patients.	4.3	3.9	3.8	3.7	3.9
Study teams care about study patients as people.	4.4	3.8	3.7	3.5	3.5
Patients who take part in studies follow instructions carefully, including taking the drug exactly as they are supposed to.	4.1	3.6	3.5	3.5	3.6
Studies are designed to look at the possible benefits of drugs in an honest, unbiased way.	4.1	3.7	3.4	3.4	3.6
Studies are designed to look at the possible risks of drugs in an honest, unbiased way. *	4.2	3.6	3.4	3.3	3.6
Pharmaceutical companies report on study data in an honest and unbiased way.	3.9	3.4	3.2	3.3	3.3
Pharmaceutical companies carefully monitor the well-being of study patients.	3.8	3.4	3.3	3.2	3.2
Pharmaceutical companies care about study patients as people.	3.6	3.1	3.1	3.0	2.6
N range=	14-20	162-182	160-177	59-65	9-12

Note: Highest mean per row highlighted in yellow, lowest in red. * p<.05; ** p<.01; ***p<.005 ; ****p<.0001 (unadjusted for multiple tests)

Patients' Confidence in Trial Compliance/Ethics: By Family Responsibility

On average, patients who were responsible for providing direct care or financial support of family members were more skeptical about the compliance, ethics, and caring of those executing clinical trials than were those who were not.

Confidence in Clinical Trial Compliance and Ethics by Family Responsibility

Mean ratings on a scale of 1 (not at all confident) to 5 (very confident)	**Yes (provides care or financial support to family members)**	**No**
Study teams collect patient study data in an honest and unbiased way. *	3.8	4.1
Study teams perform the studies exactly the way they are supposed to. *	3.8	4.0
Study teams collect patient data with enough attention to detail to "get it right." *	3.7	4.0
Study teams carefully monitor the well-being of study patients.	3.7	3.9
Study teams care about study patients as people.	3.7	3.7
Patients who take part in studies follow instructions carefully, including taking the drug exactly as they are supposed to.	3.4	3.7
Studies are designed to look at the possible benefits of drugs in an honest, unbiased way. *	3.4	3.6
Studies are designed to look at the possible risks of drugs in an honest, unbiased way. *	3.3	3.6
Pharmaceutical companies report on study data in an honest and unbiased way. *	3.2	3.4
Pharmaceutical companies carefully monitor the well-being of study patients.	3.2	3.4
Pharmaceutical companies care about study patients as people.	2.9	3.1
N range=	165-186	246-270

Note: Highest mean per row highlighted in yellow, lowest in red. * p<.05; ** p<.01; ***p<.005 ; ****p<.0001 (unadjusted for multiple tests)

Patient Views on Actions that Influence Confidence

Themes in Open-Ended Comments

- Interaction with patients for feedback about study design and operations
  - *"They don't interact with participants to get feedback on what was good or bad about the study."*
  - *"Evidence of including patient participation in trials' creation, monitoring, and measurement of assessment using viable tools."*

- Fair compensation, and caring, respectful, and equitable treatment as participants in the research process:
  - *"While the protocol is patient-centered, the back-up and bedside manner do not always work."*
  - *"Care about patients as people? Ha! Then why are we called 'subjects'?? And why aren't we compensated much better and sooner in the study? The sponsors make obscene amounts of money and skip when it comes to all aspects of patient interaction. Why are the visits always so inconvenient? Why aren't there evening and weekend hours? Why aren't staff trained in interpersonal communication, especially the chief investigating physician?"*
  - *"It boils down to their taking time with me. Being transparent about what they are doing step-by-step and explaining what is going on."*

Patient Views on Actions that Influence Confidence

Themes in Open-Ended Comments, *continued*

- A very large number of comments had to do with business concerns. While patients were most likely to cite the profit motives of pharmaceutical companies or medical practitioners as a huge source of distrust, some also derived confidence from this fact, reflecting that "finding the truth" made good business sense and that any unethical conduct would return poorly in the long term both in terms of product investments and in terms of liabilities.
  - *"The medical and pharmaceutical industries' main priority is money! When money is the most important thing, people are not told complete information. It's a basic conflict of interest!"*
  - *"Re. doctors' motivations, I don't remember this particular aspect of either trial we participated in, or the various other trials I considered, ever having been mentioned."*
  - *"I think most of them understand that for long-term success they need to develop drugs that are good for both patients and their company, so incentives are aligned in some respect."*
  - *"I've been to conferences where the main speaker is trying to convince people to participate in clinical trials. None of the side effects were addressed. It was truly a 'sales pitch.'"*

Patient Views on Actions that Influence Confidence

Themes in Open-Ended Comments, *continued*

- Many patients report that their confidence in the teams performing clinical studies comes largely from their faith that these parties are governed by regulations and monitoring bodies (including ethics committees), and fearful of lawsuits.
- Many also report confidence simply in the professionalism and good intentions of researchers, practitioners, and institutions operating in the medical field.
- Perceived transparency in the areas of study procedures, study results, drug risks, IRB interactions, doctor motivations, etc. was regarded as a source of confidence by patients who had experienced such transparency. Conversely, a lack of transparency in these respects, particularly in the dissemination of results, was cited as a source of distrust.
  - *"The team…made sure I understood everything about the study and was quick to respond when any question came up."*
  - *"I asked for feedback after the study I did participate in and never received it. I know of no-one who trusts pharmaceutical companies." "I feel as though I have been forgotten."*
- Media reports regarding corruption and drug recalls, and lawyer's advertisements regarding class action suits, were cited as sources of distrust in the industry.

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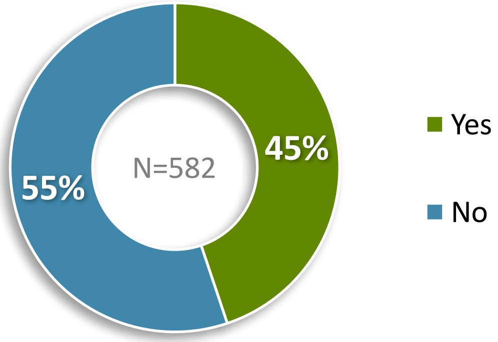
Perspectives on Clinical Trial Participation

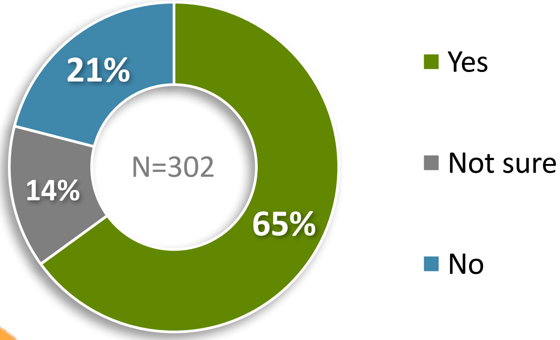
Patient Survey: Clinical Trial Participation Rate and Reasons

Nearly half of the patient surveyed had participated in a clinical trial. The most common reason for doing so was the opportunity to contribute to science, followed by the opportunity to learn more about their conditions and by payment for participation. The majority of clinical trial participants reported feeling more educated and involved in their overall health as a result.

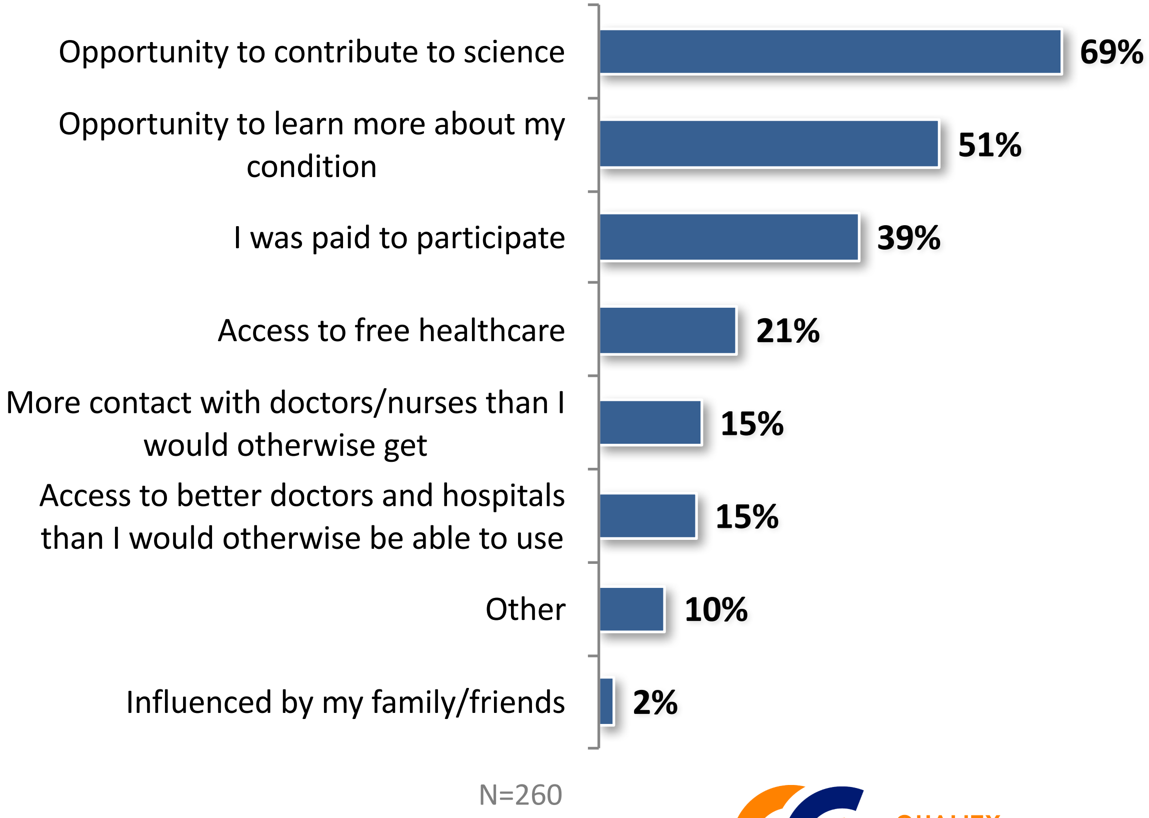
Have you ever participated in a clinical trial?



If yes, did you feel more educated and involved in your overall health as a result?



Why did you decide to participate in the clinical trial?



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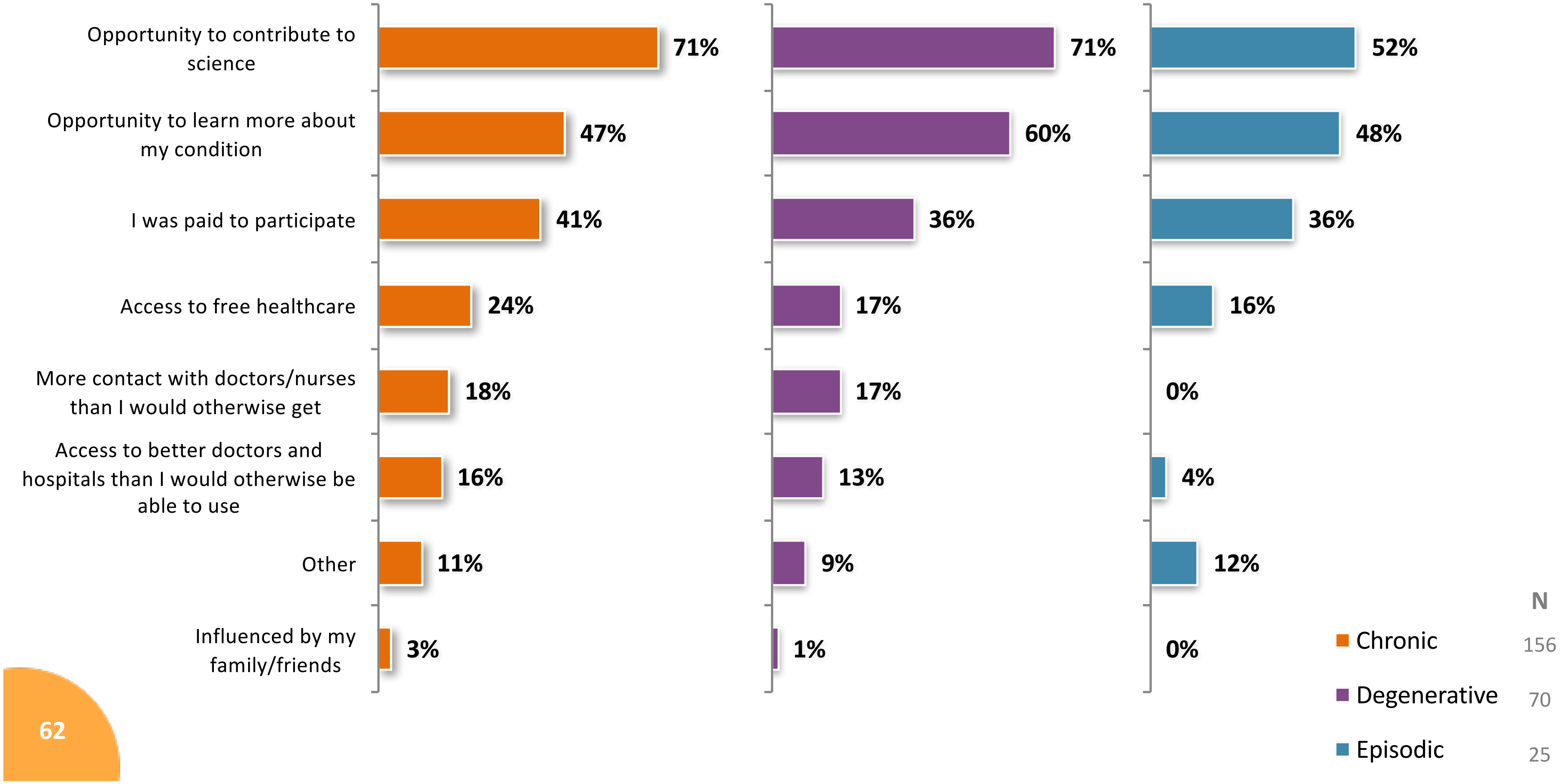
Patient Subsets: Type of Medical Condition

There were some differences across patients with different types of medical conditions in the reasons for deciding to participate in clinical trials. Although the top four reasons were all the same, and in the same order, patients with chronic and degenerative conditions generally endorsed more reasons for trial participation than did those with episodic conditions, particularly including a desire for more contact with doctors/nurses, and access to better hospitals and doctors, than they would otherwise get.

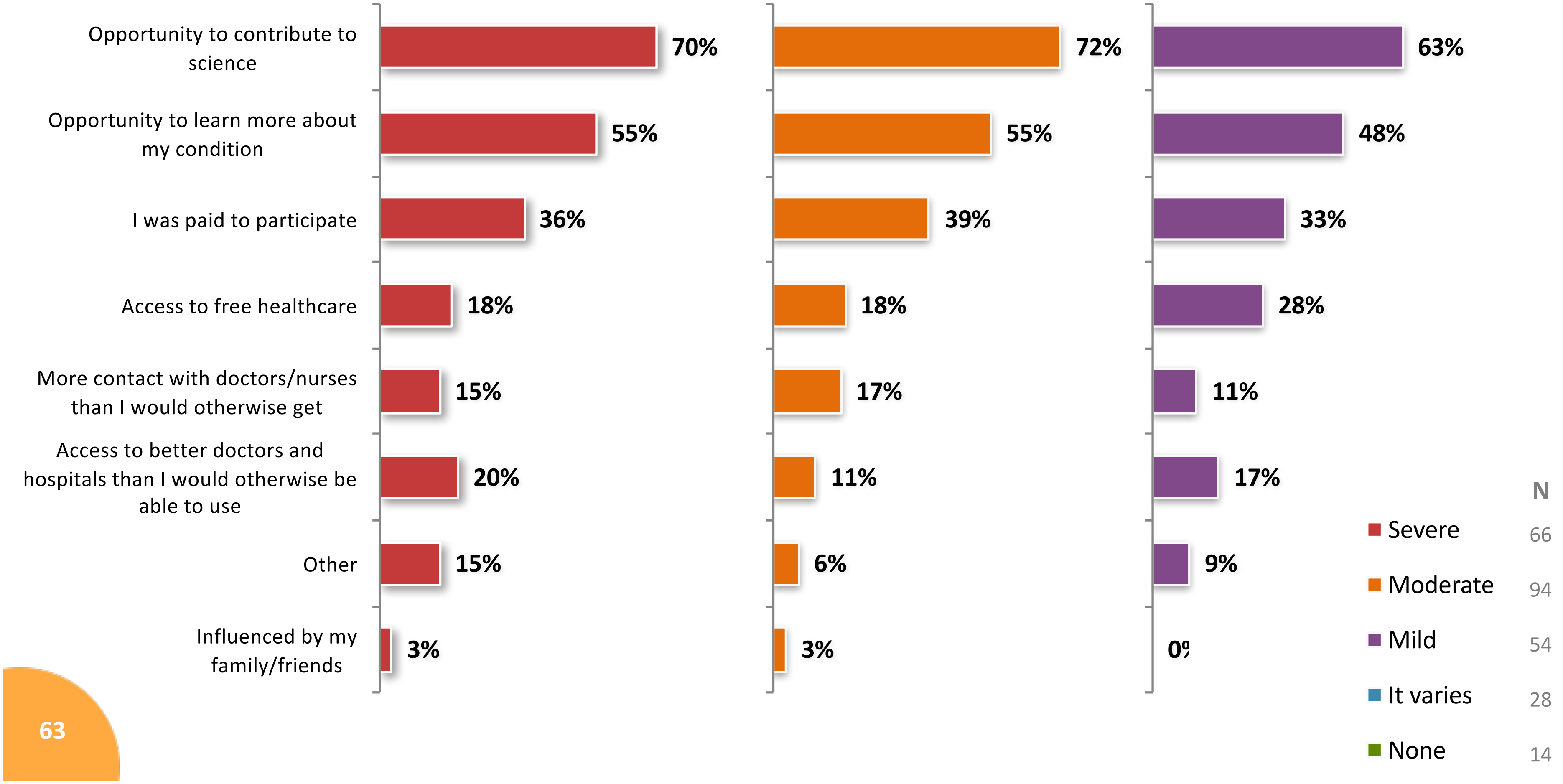
Why did you decide to participate in the clinical trial? by Type of Medical Condition



Patient Subsets: Impact of Medical Condition

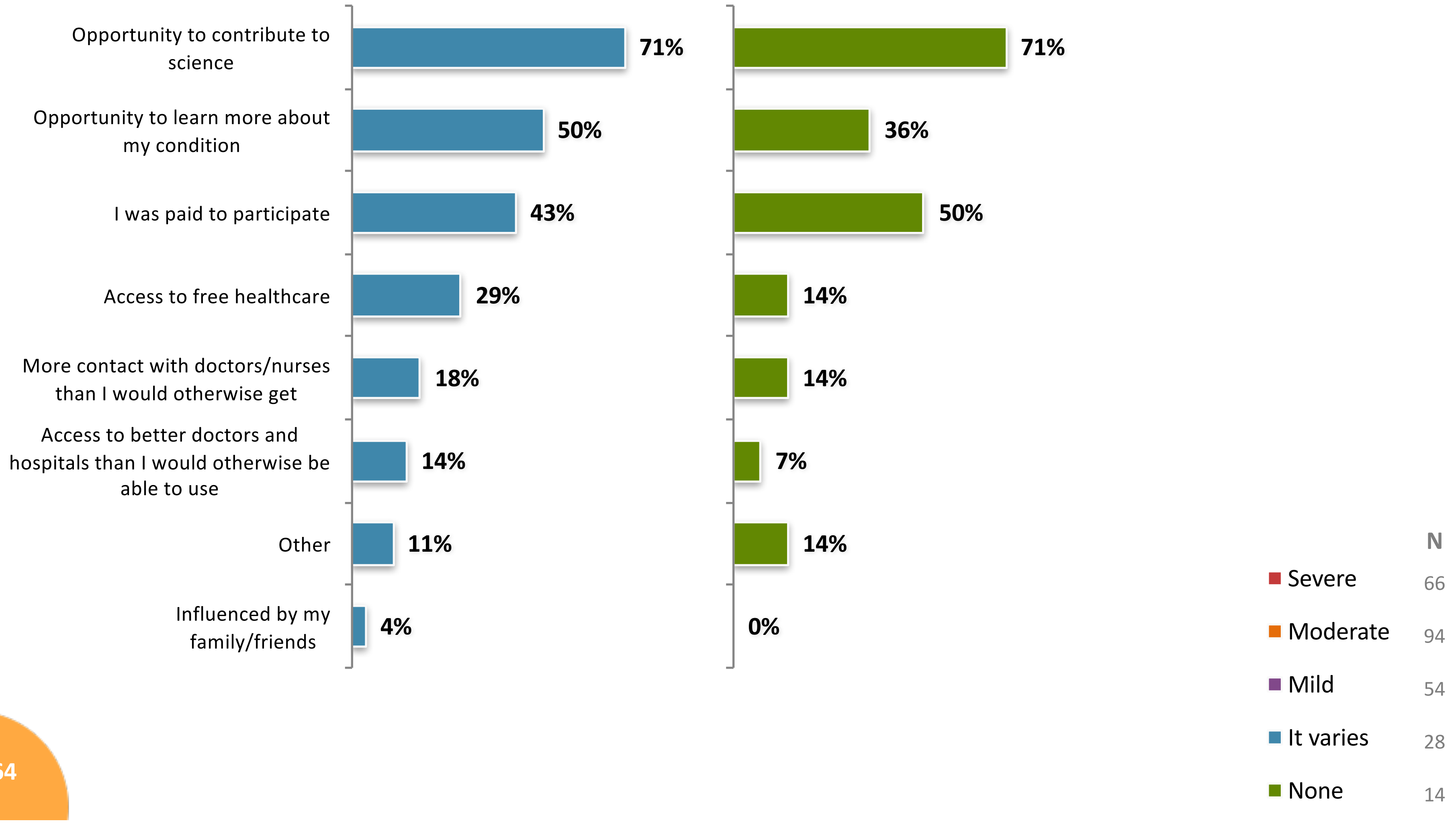
There were also differences across patients with different severities of medical conditions. Although again the top three reasons for trial participation were all the same, patients with mild disease were more likely to be influenced by access to free healthcare than were those with more serious conditions, and those with no impact were more likely to be influenced by payment (see next slide).

Why did you decide to participate in the clinical trial? by Impact of Medical Condition



Patient Subsets: Impact of Medical Condition (continued)

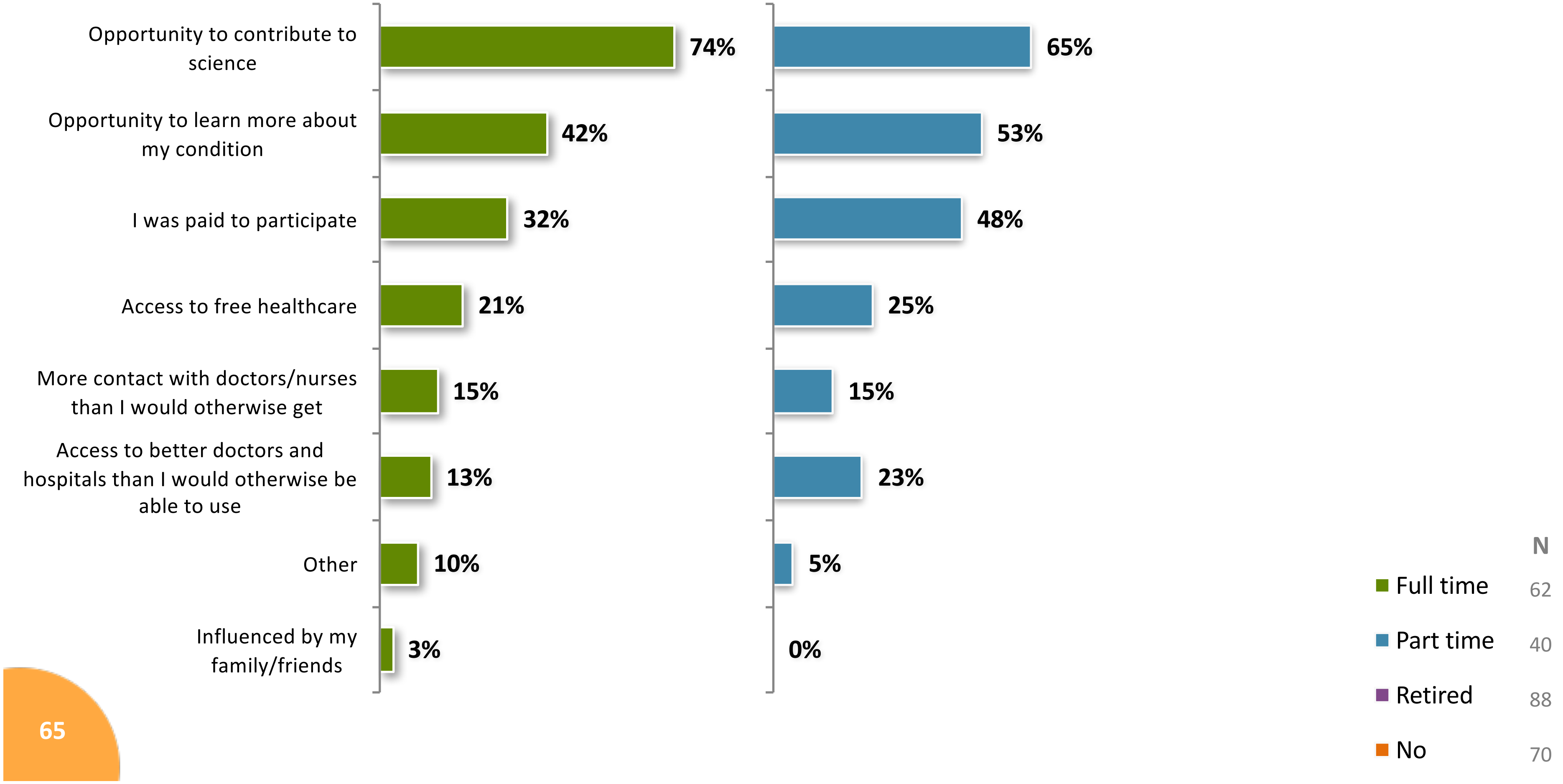
Why did you decide to participate in the clinical trial? by Impact of Medical Condition



Patient Subsets: Employment Status

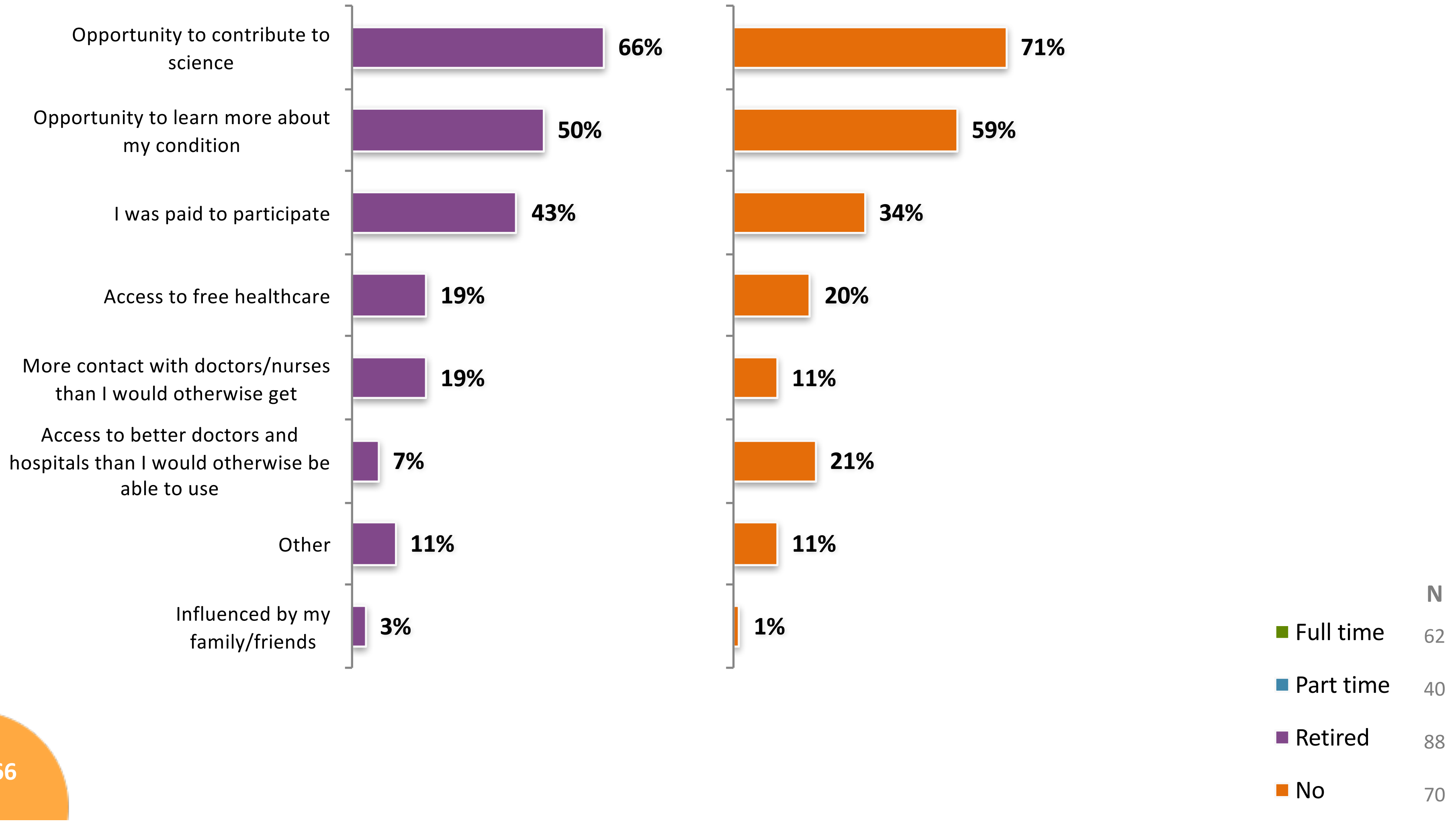
Not surprisingly, employment status also influenced patients' decision-making criteria (this slide and next). Again the top three reasons for trial participation were all the same, however, fully employed patients were less likely than others to be influenced by payment or by the opportunity to learn about their conditions, and more likely to be influenced by the chance to contribute to science.

Why did you decide to participate in the clinical trial?
by Current Employment



Patient Subsets: Employment Status (continued)

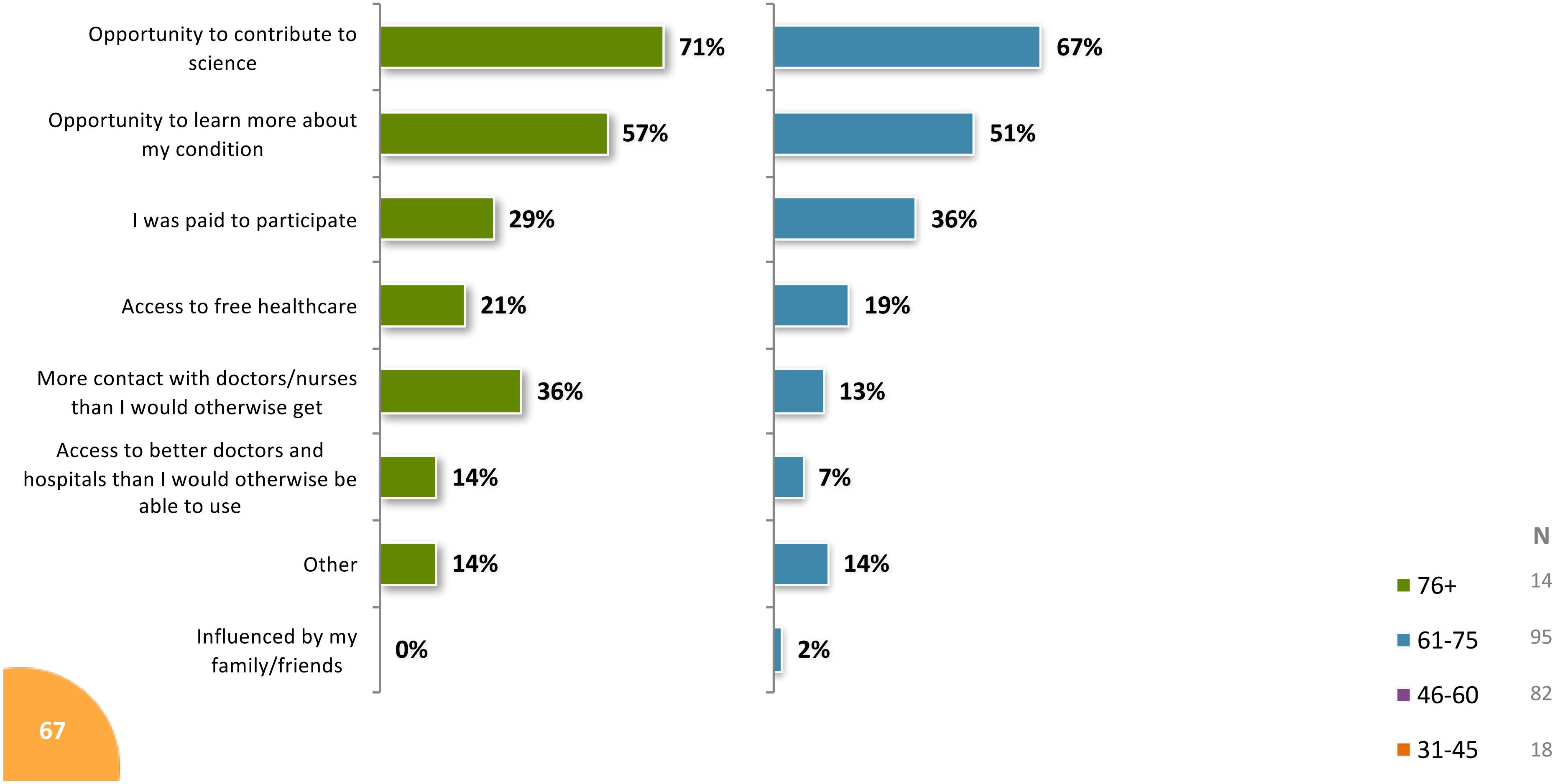
Why did you decide to participate in the clinical trial? by Current Employment



Patient Subsets: Age Group

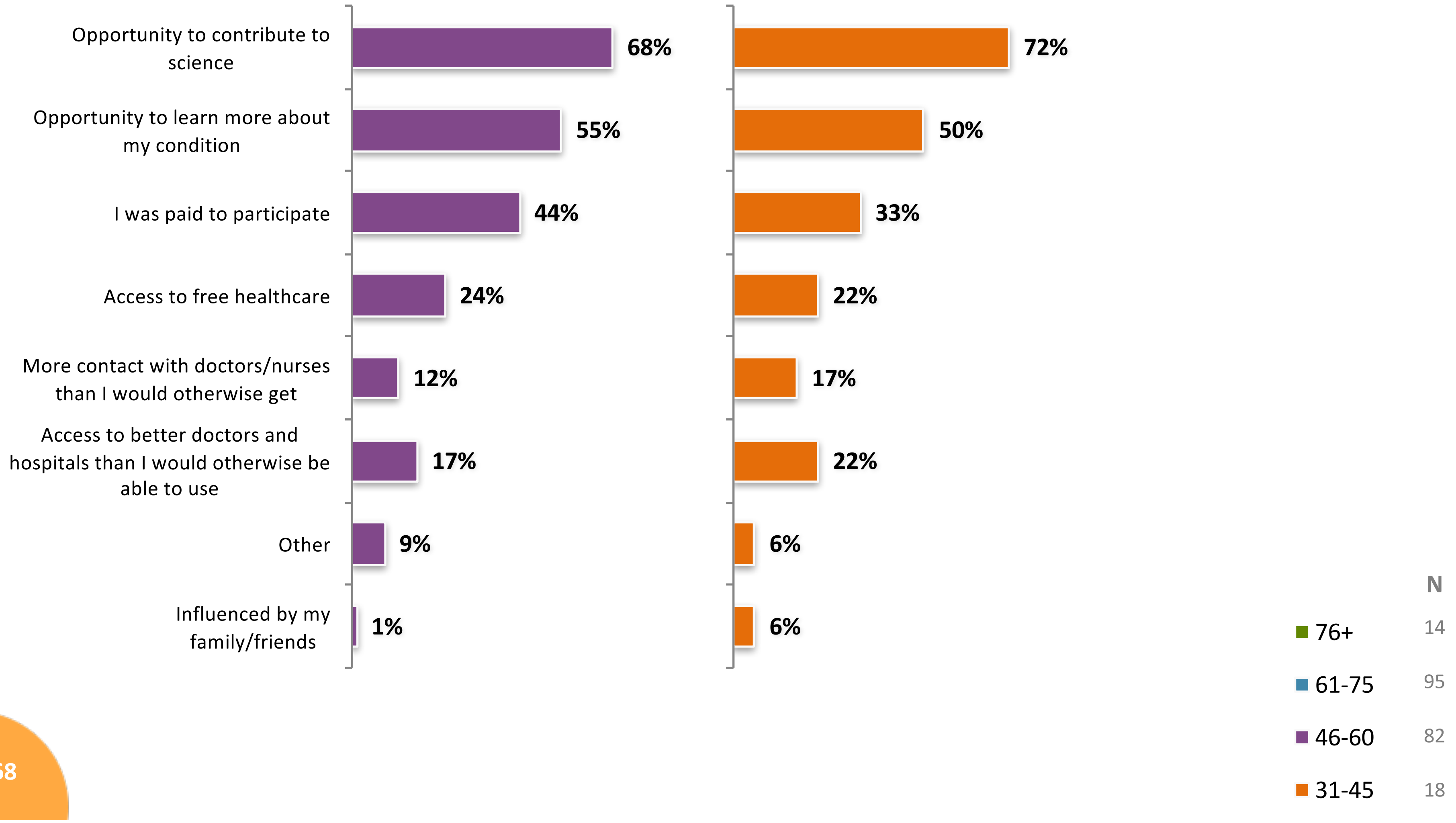
Age group appeared to have a substantial impact on patients' decision-making criteria (this slide and next), though the Ns in some groups were small. For older patients (76+), the additional expected contact with doctors and nurses was a key reason for participation, whereas for younger patients (31-60), access to better doctors and hospitals was more likely to be a key factor.

Why did you decide to participate in the clinical trial?
by Age (only categories with N>10)



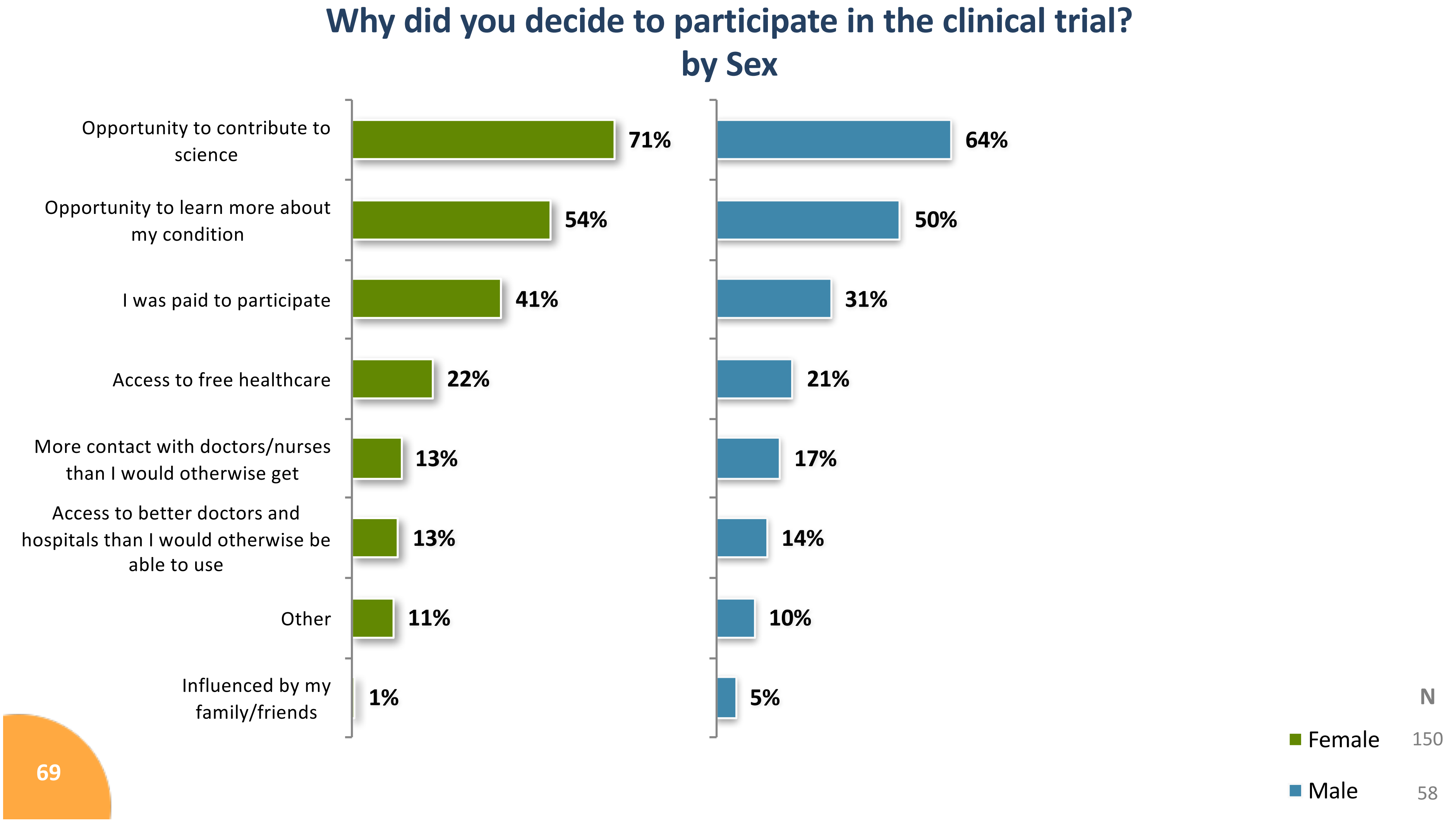
Patient Subsets: Age Group (continued)

Why did you decide to participate in the clinical trial? by Age



Patient Subsets: Sex

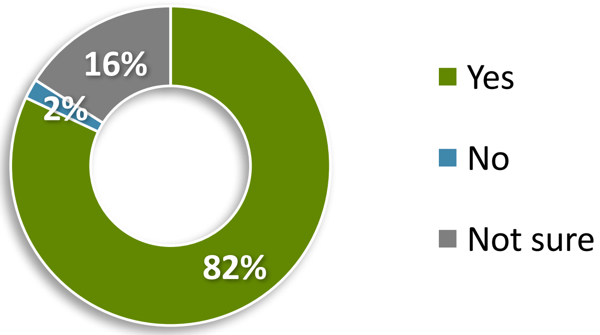
Females in general endorsed more reasons for participating in clinical trials than did males, though the overall pattern of top reasons was the same.



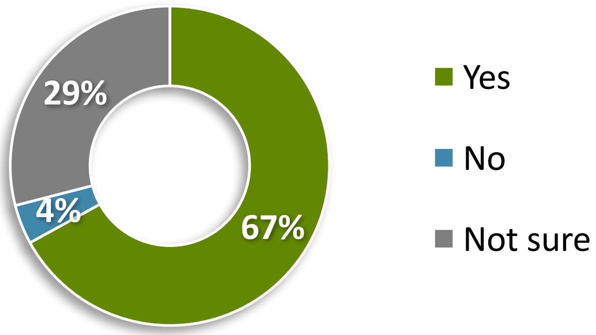
Willingness to Recommend Clinical Research Participation

The majority of both AQC Members and Patients stated that they would recommend clinical research participation to a loved one or friend, but many in each group stated that they weren't sure. Among those not sure, severity of disease and availability of other options were volunteered as comments for ambivalence.

Sponsor/CRO AQC Members



Patients



Sponsor N=102, CRO N=85; Patients N=422

Q: Based on your experience, would you recommend clinical research participation to a loved one or friend?

Patients: Clinical Trial Participation

Among those who responded “Yes”, responses carried themes of consideration of risks and benefits, of the institutions at which the studies are being performed, and of a wish to “do good” for society. “No” responses generally reflected distrust of the industry.

- *“It would depend on the drugs involved, length of time, and severity of my friend’s condition.”*
- *“If it’s a double-blind trial with placebo, then I’m hesitant to participate or recommend participation because I might wind up going without medication for a condition that needs medicating.”*
- *“I only do it for the money.”*
- *“If more people don’t participate in clinical research, then they might as well consider themselves as being experimented on with marketed drugs.”*
- *“Don’t go in blind and dumb. Ask plenty of questions. It would help if patients got a crash course in what the study was about and what to expect in the form of a pamphlet. Never seen that before. Everything is vague, politically correct, and general…We also need to be compensated better, like we matter as much as the rest of the study team.”*
- *“Science needs all the help it can get.”*
- *“I want to help people. Even if I end up in the placebo group.”*

Patients N=422

Q: Based on your experience, would you recommend clinical research participation to a loved one or friend?

AQC Members: Clinical Trial Participation

Among those who responded “Yes”, responses carried a common theme of dire circumstance (life threatening disease/absence of other options) and consideration of risks and benefits. “No” responses did not offer comments.

- *“I would participate in a clinical trial myself if it was for treatment for a condition I was suffering from and I believed that this trial could benefit me and society.”*
- *“Of course, I would say that not all trials are created equal and the loved one or friend should evaluate the consent document carefully, ask lots of questions, and ask for additional sources of information.”*
- *“If there are limited treatments which are approved and available to a family member, I would definitely recommend a clinical trial approach.”*
- *“Phase I healthy volunteers with NME - NO! If loved-one/friend had a life-threatening disease and treatment options were limited then I would recommend they find out about appropriate clinical trial.”*
- *“Oncology, for sure. Less confident about other indications.”*
- *“There needs to be more information for patients on trials, and more trials in critical areas (e.g. autism).”*
- *“I would for sure recommend participation in a trial, when there is enough information given on the risk-benefit ratio, side effects and other potential treatments outside of a trial.”*
- *“I would recommend EXPLORING clinical trial research participation based on the ethics applied by the companies that generally sponsor and execute them, but clinical research comes with inherent risk; the potential risks need to be well understood before committing.”*

Sponsor N=102, CRO N=85

Q: Based on your experience, would you recommend clinical research participation to a loved one or friend?

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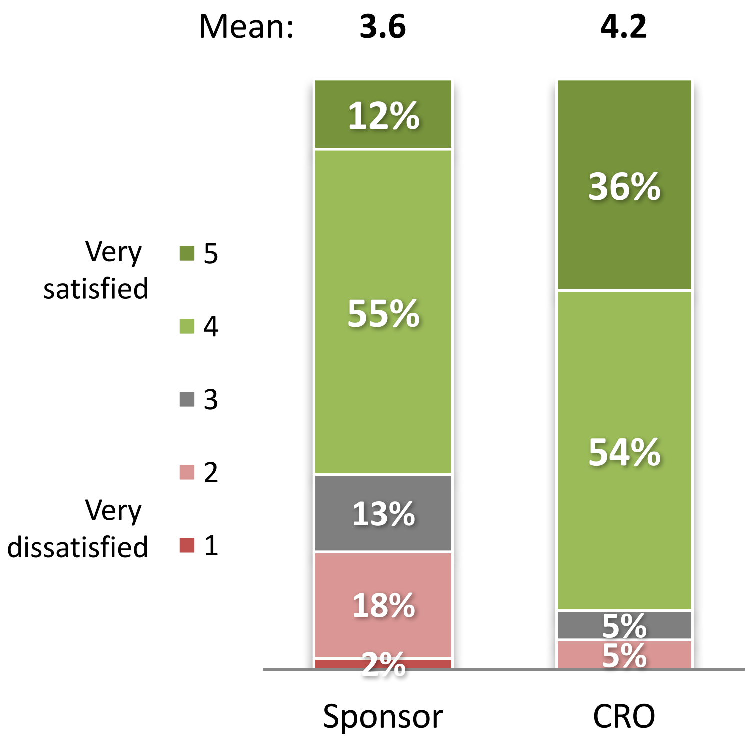
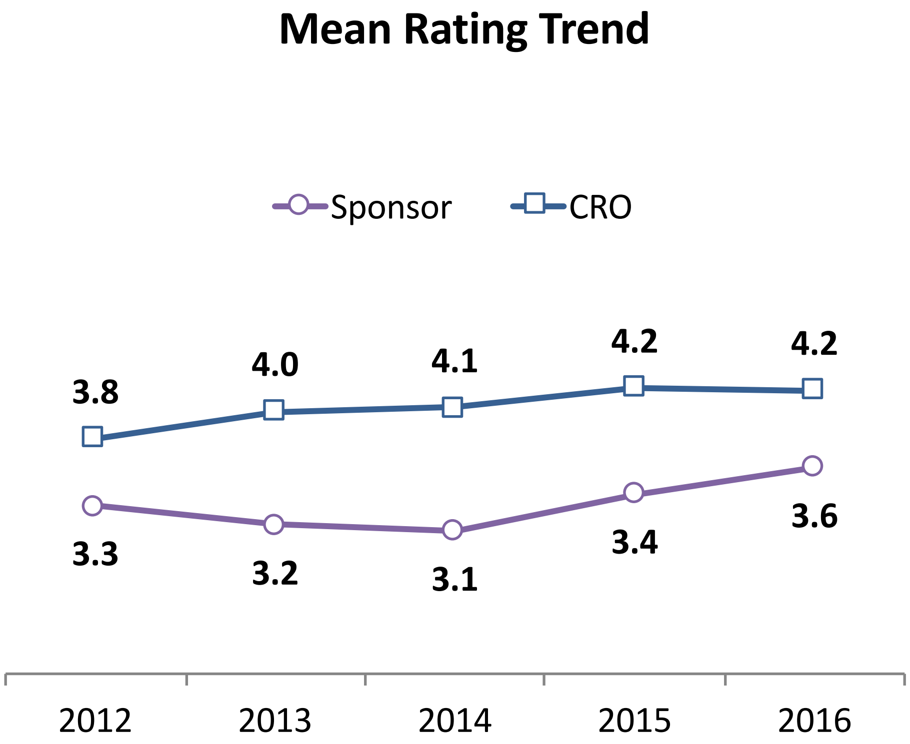
AQC Member Survey: Perceptions of Clinical Research Quality

Perceptions of Quality Over Time

Though there continues to be a difference between CRO satisfaction with quality delivered and satisfaction with quality received among Sponsors, an upward trend in Sponsor ratings is driving a move towards convergence at an overall higher level of satisfaction with quality delivered as compared to 2012.




Mean Rating Trend

Sponsor N=101, CRO N=85

Sponsor Q: Thinking about your experiences with Clinical Service Providers you worked with in 2015, how satisfied are you with…the quality delivered by your Clinical Service Providers?

Provider Q: Thinking about your experiences in 2015, how satisfied are you with…the quality that your company delivered to Sponsors?

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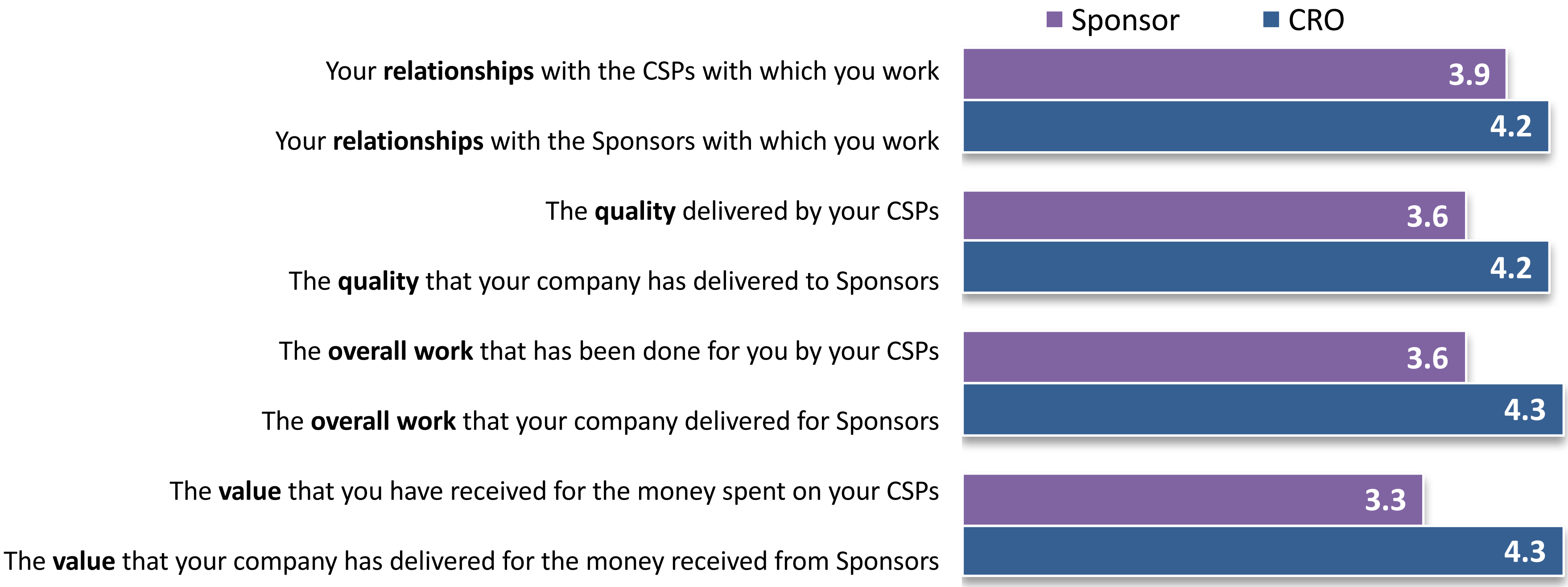
Satisfaction on Key Relationship Metrics

Sponsors and CROs are closely aligned in their satisfaction with relationships, however they differ in their perception of satisfaction with respect to quality, overall work delivered and value for money.



Sponsor N=92-101, CRO N=82-85

Sponsor Q: Thinking about your experiences with Clinical Service Providers you worked with in 2015, how satisfied are you with…

Provider Q: Thinking about your experiences in 2015, how satisfied are you with…

The Avoca Quality Consortium brings together quality, outsourcing and operational professionals from member pharma, biotech, niche clinical service providers, and CRO organizations to accelerate and streamline clinical trial execution and improve quality through industry collaboration.

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Thank you

Contact Avoca at:
(609) 252-9020
www.theavocagroup.com
info@theavocagroup.com

179 Nassau Street, Suite 3A
Princeton, NJ 08542