

# Results from 2005 Survey of the Clinical Trials Industry

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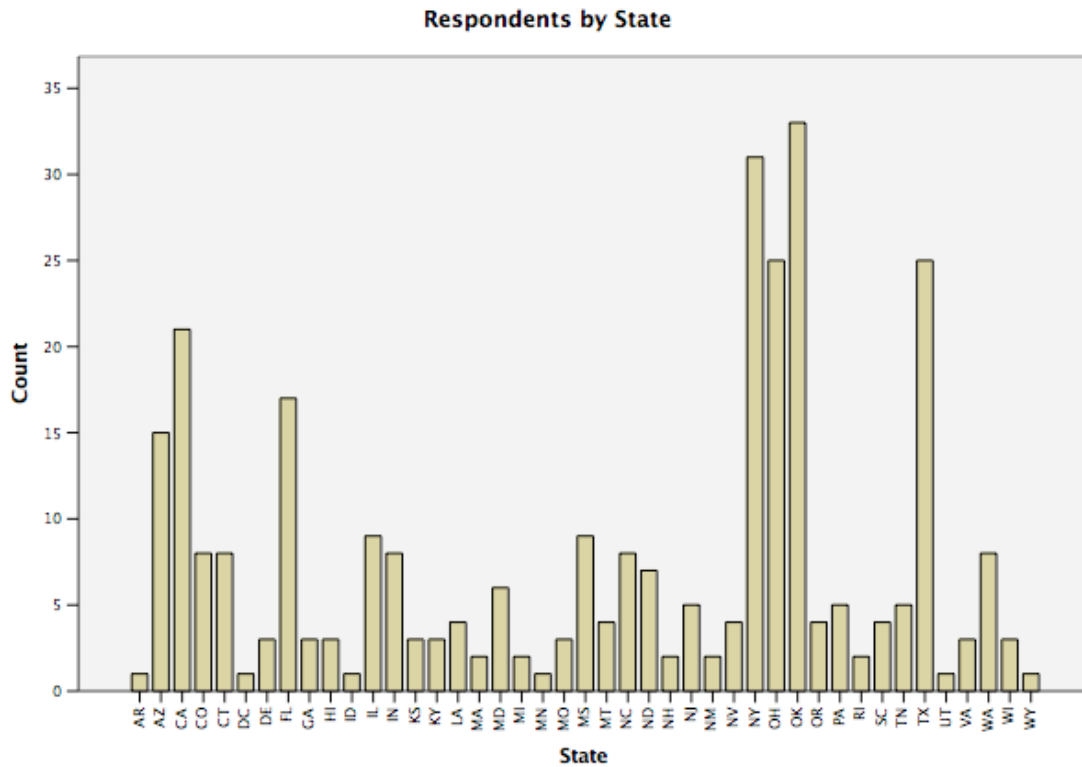
## Total Respondents: 313

### Demographics of respondents:

The statistics indicate the number (and percent) of respondents who selected the answer listed.

- Age
  - Average (median) = 44.0 (Range = 22 - 69)
- Sex
  - Female = 253 (81%)
  - Male = 59 (19%)
- Race / Ethnicity
  - American Indian or Alaska Native = 5 (1.6%)
  - Asian = 9 (2.9%)
  - Black or African American = 14 (4.5%)
  - Native Hawaiian or Other Pacific Islander = 2 (0.6%)
  - White, Hispanic = 27 (8.6%)
  - White, Non-Hispanic = 252 (80.8%)
- Education
  - High School or equivalent = 7 (2.2%)
  - Trade / Certificate = 19 (6.1%)
  - College (including associates, bachelors, and incomplete degrees) = 171 (54.6%)
  - Masters degrees = 65 (20.8%)
  - MD/DO degrees = 23 (7.3%)
  - Doctorate degrees = 19 (6.1%)
- Current Organization
  - Academic medical centers = 82 (26.2%)
  - Community, Teaching, and VA hospitals (non-university affiliated) = 35 (11.1%)
  - Contract research organizations (CRO), Trial management organizations (TMO), and Recruitment/marketing firms = 26 (8.3%)
  - Dedicated investigative sites, non-SMO = 46 (14.7%)
  - Private practices, non-SMO = 88 (28.1%)
  - Site management organizations (SMO) = 25 (8.0%)
  - Pharmaceutical / Biotechnology companies = 7 (2.2%)
  - Independent contractors = 2 (0.6%)

- Current Position and Average Income
  - Administrators = 76 (24.3%)
    - Median income = \$75,000 (Range = \$10,000 - \$1,500,000)
  - Monitors (CRAs) = 12 (3.8%)
    - Median income = \$74,000 (Range = \$48,000 - \$200,000)
  - Pharmaceutical company employees (e.g., project managers, scientific liaisons, etc.) = 6 (1.9%)
    - Median income = \$118,000 (Range = \$72,500 - \$300,000)
  - Principal investigators (PIs) = 21 (6.7%)
    - Median income = \$190,000 (Range = \$100,000 - \$600,000)
  - Research coordinators (CRCs) = 162 (51.8%)
    - Median income = \$45,000 (Range = \$10,000 - \$170,000)
  - Sub-investigators (Sub-I) = 10 (3.2%)
    - Median income = \$80,000 (Range = \$65,000 - \$200,000)
  - Other site staff (e.g., recruiting, regulatory, quality assurance) = 18 (5.8%)
    - Median income = \$40,000 (Range = \$26,000 - \$85,000)
  - Other off-site staff (e.g., third party recruiters, study brokers, etc.) = 7 (2.2%)
    - Median income = \$50,000 (Range = \$23,000 - \$150,000)
- Experience
  - Years in healthcare sector (median) = 18 (Range = 1 - 45)
  - Years in clinical trials industry (median) = 7 (Range = 1 - 29)
- Location of respondents



## Results from Selected Survey Questions

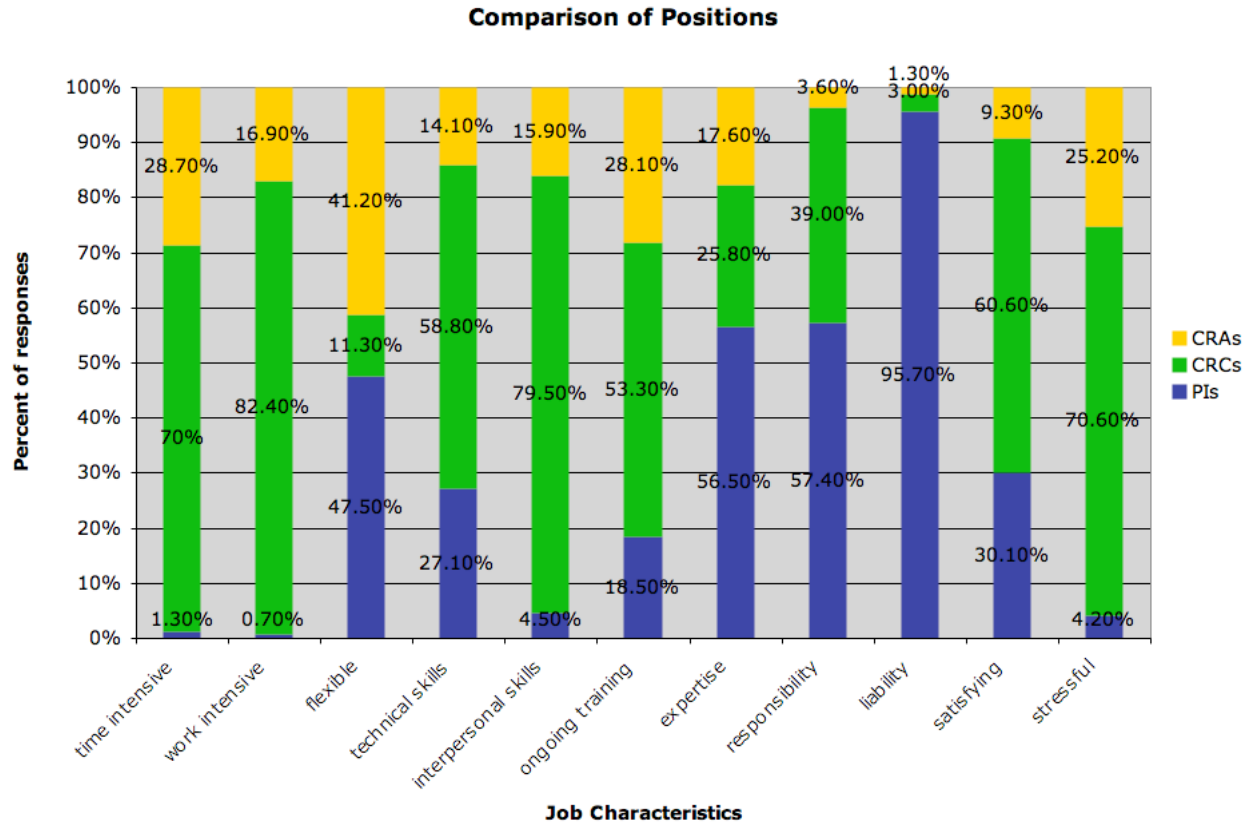
### Involvement in clinical trials

The first section of the questionnaire asked respondents to consider the reasons why people get involved in clinical trials. Respondents were given the option of checking three items that they considered to be the top reasons that physicians, coordinators, monitors, and human subjects participate in clinical research. The results for each of these groups is reported below. The statistics indicate the number (and percent) of respondents who selected the answer.

- ❖ “Check the top 3 reasons you think most physicians get involved in clinical research.”
  1. **Increase revenue = 169 (64.3%)**
  2. **Provide options for patients = 140 (53.2%)**
  3. **Desire to stay up-to-date on medical advances = 131 (49.8%)**
  4. **Desire to contribute to science = 126 (47.9%)**
  5. Increase individual prestige = 68 (25.9%)
  6. Enhance standing of private practice = 55 (20.9%)
  7. Intellectual reward = 52 (19.8%)
  8. Asked to do so by partner, boss, etc. = 34 (12.9%)
  9. More time for personal life = 4 (1.5%)
  10. Decrease malpractice liability = 2 (0.8%)
  
- ❖ “Check the top 3 reasons you think most coordinators take their jobs in clinical research.”
  1. **Career advancement = 142 (54.0%)**
  2. **Better working conditions = 109 (41.4%)**
  3. **Desire to contribute to science = 97 (36.9%)**
  4. **Increase wages = 89 (33.8%)**
  5. Intellectual reward = 76 (28.9%)
  6. Provide options for patients = 73 (27.8%)
  7. Asked to do so by physician, boss, etc. = 68 (25.9%)
  8. Desire to stay up-to-date on medical advances = 54 (20.5%)
  9. Make more time for personal life = 42 (16.0%)
  10. Increase individual prestige = 33 (12.5%)
  
- ❖ “Check the top 3 reasons you think most monitors take their jobs in clinical research.”
  1. **Career advancement = 226 (85.9%)**
  2. **Increase wages = 216 (82.1%)**
  3. **Desire to travel = 146 (55.5%)**
  4. Asked to do so by contacts at a CRO, pharmaceutical company, etc. = 64 (24.3%)
  5. Increase individual prestige = 51 (19.4%)
  6. Desire to contribute to science = 30 (11.4%)
  7. Intellectual reward = 23 (8.7%)
  8. Desire to stay up-to-date on medical advances = 19 (7.2%)
  
- ❖ “Check the top 3 reasons you think most patient-subjects participate in clinical research.”
  1. **To receive access to free medical care and medications = 197 (74.9%)**
  2. **Best or only option for treatment = 149 (56.7%)**
  3. **Asked to do so by physician, coordinator, etc. = 142 (54.0%)**
  4. Desire to contribute to science = 117 (44.5%)
  5. Financial incentives = 98 (37.3%)
  6. Higher quality medical care = 70 (26.6%)
  7. Influenced by family or friends = 9 (3.4%)

## Comparing positions in clinical trials work

One of the sections of the questionnaire asked respondents how the positions of PIs, coordinators, and monitors generally compare on specific employment characteristics. The following figure indicates **the percentage of respondents who selected each position** (PI, coordinator - CRC, and monitor - CRA) as the most 1) time intensive, 2) work intensive, and 3) flexible. It also indicates the percentage of respondents who thought which position requires the most 4) technical skills, 5) interpersonal skills, 6) ongoing training, 7) expertise, 8) responsibility, 9) liability. Finally, the figure indicates the percentage of respondents who perceive each job as the most 10) satisfying/rewarding and 11) stressful.



## Physicians as principle investigators

The next section asked respondents questions about physicians as principle investigators. The following are results generated from specific questions in that series.

- ❖ “Clinical trials can be conducted by any practicing physician.”
  - ▶ Strongly Agree = 13 (4.2%)
  - ▶ Agree = 66 (21.6%)
  - ▶ Neither Agree nor Disagree = 33 (10.8%)
  - ▶ **Disagree = 135 (44.1%)**
  - ▶ Strongly Disagree = 59 (19.3%)
  
- ❖ “PIs should only conduct studies in their therapeutic area of expertise.”
  - ▶ **Strongly Agree = 106 (34.5%)**
  - ▶ **Agree = 126 (41.0%)**
  - ▶ Neither Agree nor Disagree = 33 (10.7%)
  - ▶ Disagree = 38 (12.4%)
  - ▶ Strongly Disagree = 4 (1.3%)

- ❖ “Most PIs are not as involved as they should be with their clinical studies.”
  - ▶ Strongly Agree = 60 (19.6%)
  - ▶ **Agree = 153 (50.0%)**
  - ▶ Neither Agree nor Disagree = 50 (16.3%)
  - ▶ Disagree = 39 (12.7%)
  - ▶ Strongly Disagree = 4 (1.3%)
- ❖ “PIs set the ethical tone of sites; research staff will only be as ethical as are the PIs.”
  - ▶ Strongly Agree = 49 (16.1%)
  - ▶ **Agree = 80 (26.3%)**
  - ▶ Neither Agree nor Disagree = 34 (11.2%)
  - ▶ **Disagree = 111 (36.5%)**
  - ▶ Strongly Disagree = 30 (9.9%)
- ❖ “PIs' enrollment of patient-subjects is affected by financial incentives to fill studies.”
  - ▶ Strongly Agree = 18 (5.9%)
  - ▶ **Agree = 86 (28.4%)**
  - ▶ **Neither Agree nor Disagree = 71 (23.4%)**
  - ▶ **Disagree = 104 (34.3%)**
  - ▶ Strongly Disagree = 24 (7.9%)
- ❖ “PIs' financial conflicts of interest can be greatly reduced by putting PIs on salary.”
  - ▶ Strongly Agree = 9 (3.0%)
  - ▶ Agree = 33 (10.8%)
  - ▶ **Neither Agree nor Disagree = 130 (42.6%)**
  - ▶ **Disagree = 103 (33.8%)**
  - ▶ Strongly Disagree = 30 (9.8%)
- ❖ “Indicate which of the following you think are important traits for PIs.”
  - ▶ The top five traits for PIs that were selected by more than 65% of respondents were 1) **conscientious** (81.3%), 2) **truthful** (74.0%), 3) **reliable** (73.7%), 4) **efficient** (69.4%), and 5) **compassionate** (65.8%).

## Research Coordinators

The next section asked respondents questions about research coordinators. The following are results generated from specific questions in that series.

- ❖ “The more obsessive-compulsive coordinators are, the better they do their jobs.”
  - ▶ Strongly Agree = 40 (13.3%)
  - ▶ **Agree = 120 (39.9%)**
  - ▶ Neither Agree nor Disagree = 64 (21.3%)
  - ▶ Disagree = 67 (22.3%)
  - ▶ Strongly Disagree = 10 (3.3%)
- ❖ “A big part of the coordinator job has to do with ethics.”
  - ▶ Strongly Agree = 113 (37.5%)
  - ▶ **Agree = 150 (49.8%)**
  - ▶ Neither Agree nor Disagree = 23 (7.6%)
  - ▶ Disagree = 14 (4.7%)
  - ▶ Strongly Disagree = 1 (0.3%)

- ❖ “Coordinators should encourage patient-subjects to drop out of trials if the patient-subjects feel that they have received a placebo.”
  - ▶ Strongly Agree = 4 (1.3%)
  - ▶ Agree = 3 (1.0%)
  - ▶ Neither Agree nor Disagree = 24 (7.9%)
  - ▶ Disagree = 119 (39.4%)
  - ▶ **Strongly Disagree = 152 (50.3%)**
  
- ❖ “Coordinators should encourage patient-subjects to remain in trials even when patient-subjects feel that their condition is getting worse (but they are not in physical danger).”
  - ▶ Strongly Agree = 8 (2.7%)
  - ▶ Agree = 28 (9.3%)
  - ▶ Neither Agree nor Disagree = 73 (24.3%)
  - ▶ **Disagree = 111 (36.9%)**
  - ▶ Strongly Disagree = 81 (26.9%)
  
- ❖ “Part of coordinators’ tasks should be to try to empower patient-subjects to take control of their health.”
  - ▶ Strongly Agree = 63 (21.0%)
  - ▶ **Agree = 136 (45.3%)**
  - ▶ Neither Agree nor Disagree = 67 (22.3%)
  - ▶ Disagree = 27 (9.0%)
  - ▶ Strongly Disagree = 7 (2.3%)
  
- ❖ “Coordinators should only work for PIs they respect and/or admire.”
  - ▶ Strongly Agree = 65 (21.7%)
  - ▶ **Agree = 122 (40.7%)**
  - ▶ Neither Agree nor Disagree = 89 (29.7%)
  - ▶ Disagree = 22 (7.3%)
  - ▶ Strongly Disagree = 2 (0.7%)
  
- ❖ “Indicate which of the following you think are important traits for coordinators.”
  - ▶ The top five traits for coordinators that were selected by more than 80% of respondents were 1) **efficient** (90.7%), 2) **reliable** (89.0%), 3) **conscientious** (86.3%), 4) **adaptable** (83.7%), and 5) **truthful** (82.0%).

## Monitors (CRAs)

The next section asked respondents questions about monitors (CRAs). The following are results generated from specific questions in that series.

- ❖ “In your opinion, what is the most important function of monitors?”
  1. **Helping coordinators to get clean data = 215 (68.7%)**
  2. Detecting investigator or site fraud = 35 (11.2%)
  3. Keeping sites on their time lines = 11 (3.5%)
  4. I don’t know = 9 (2.9%)
  5. Being a team builder (write-in) = 7 (2.2%)
  6. Selecting sites to conduct studies = 5 (1.6%)
  7. Ensuring the safety of subjects (write-in) = 4 (1.3%)
  
- ❖ “In general, monitors working for pharmaceutical companies are more knowledgeable about the studies than those working for CROs.”
  - ▶ Strongly Agree = 34 (11.5%)
  - ▶ Agree = 76 (25.7%)
  - ▶ **Neither Agree nor Disagree = 111 (37.5%)**
  - ▶ Disagree = 65 (22.0%)
  - ▶ Strongly Disagree = 10 (3.4%)

- ❖ “Most sites would prefer to work with monitors from pharmaceutical companies than those from CROs.”
  - ▶ Strongly Agree = 36 (12.2%)
  - ▶ Agree = 77 (26.1%)
  - ▶ **Neither Agree nor Disagree = 130 (44.1%)**
  - ▶ Disagree = 47 (15.9%)
  - ▶ Strongly Disagree = 5 (1.7%)
  
- ❖ “Monitors that are assigned studies in only one or two therapeutic areas are better at their jobs than are monitors who do all types of studies.”
  - ▶ Strongly Agree = 57 (19.3%)
  - ▶ **Agree = 145 (49.0%)**
  - ▶ Neither Agree nor Disagree = 60 (20.3%)
  - ▶ Disagree = 30 (10.1%)
  - ▶ Strongly Disagree = 4 (1.4%)
  
- ❖ “In general, monitors can teach PIs a lot about clinical trials.”
  - ▶ Strongly Agree = 26 (8.8%)
  - ▶ **Agree = 141 (47.6%)**
  - ▶ Neither Agree nor Disagree = 79 (26.7%)
  - ▶ Disagree = 46 (15.5%)
  - ▶ Strongly Disagree = 4 (1.4%)
  
- ❖ “In general, monitors can teach coordinators a lot about clinical trials.”
  - ▶ Strongly Agree = 47 (15.9%)
  - ▶ **Agree = 150 (50.7%)**
  - ▶ Neither Agree nor Disagree = 55 (18.6%)
  - ▶ Disagree = 35 (11.8%)
  - ▶ Strongly Disagree = 9 (3.0%)
  
- ❖ “Indicate which of the following you think are important traits for monitors.”
  - ▶ The top five traits for monitors that were selected by more than 65% of respondents were 1) **efficient** (90.0%), 2) **helpful** (81.4%), 3) **reliable** (80.0%), 4) **conscientious** (79.0%), 5) **adaptable** (68.3%).

## Human Subjects

The next section asked respondents questions about human subjects volunteering for clinical trials. The following are results generated from specific questions in that series.

- ❖ “What do you think are the three most common reasons patient-subjects have for NOT participating in studies?”
  1. **Logistics of study (location, length of study, number and hours of study visits, etc.) = 187 (65.4%)**
  2. **Apprehension about getting a placebo = 165 (57.7%)**
  3. Risks associated with study = 140 (49.0%)
  4. General fear of research from negative press = 133 (46.5%)
  5. Lack of understanding about a study = 94 (32.9%)
  6. Side effects = 74 (25.9%)
  7. Types of medical procedures involved = 28 (9.8%)
  8. Amount of compensation = 22 (7.7%)
  
- ❖ “The best patient-subjects are those that volunteer for altruistic reasons.”
  - ▶ Strongly Agree = 19 (6.7%)
  - ▶ Agree = 88 (31.0%)
  - ▶ **Neither Agree nor Disagree = 131 (46.1%)**
  - ▶ Disagree = 44 (15.5%)
  - ▶ Strongly Disagree = 2 (0.7%)

- ❖ “Patient-subjects should understand the “big picture” -- the process of drug development and subjects' role in it -- before they consent to participate in any study.”
  - ▶ Strongly Agree = 29 (10.2%)
  - ▶ **Agree = 129 (45.6%)**
  - ▶ Neither Agree nor Disagree = 71 (25.1%)
  - ▶ Disagree = 52 (18.4%)
  - ▶ Strongly Disagree = 2 (0.7%)
  
- ❖ “Indicate which of the following you think are important traits for subjects.”
  - ▶ The top four traits for subjects that were selected by more than 50% of respondents were 1) **reliable** (83.5%), 2) **truthful** (76.7%), 3) **adaptable** (62.7%), and 4) **conscientious** (58.4%).
  
- ❖ “Current federal guidelines adequately protect patient-subjects in clinical trials.”
  - ▶ Strongly Agree = 52 (18.3%)
  - ▶ **Agree = 190 (66.9%)**
  - ▶ Neither Agree nor Disagree = 33 (11.6%)
  - ▶ Disagree = 8 (2.8%)
  - ▶ Strongly Disagree = 1 (0.4%)
  
- ❖ “The clinical trials industry is over-regulated.”
  - ▶ Strongly Agree = 11 (3.9%)
  - ▶ Agree = 33 (11.6%)
  - ▶ **Neither Agree nor Disagree = 109 (38.4%)**
  - ▶ **Disagree = 118 (41.5%)**
  - ▶ Strongly Disagree = 13 (4.6%)
  
- ❖ “Over all, the press negatively influences what the average person thinks about clinical trials.”
  - ▶ Strongly Agree = 49 (17.3%)
  - ▶ **Agree = 154 (54.4%)**
  - ▶ Neither Agree nor Disagree = 53 (18.7%)
  - ▶ Disagree = 27 (9.5%)
  - ▶ Strongly Disagree = 0 (0.0%)
  
- ❖ “Most Americans are aware of the negative press that clinical trials receive.”
  - ▶ Strongly Agree = 22 (7.8%)
  - ▶ **Agree = 150 (53.0%)**
  - ▶ Neither Agree nor Disagree = 51 (18.0%)
  - ▶ Disagree = 58 (20.5%)
  - ▶ Strongly Disagree = 2 (0.7%)

## Clinical trials industry

The last section asked respondents general questions about the clinical trials industry. The following are results generated from specific questions in that series.

- ❖ “Clinical trials are less profitable now than they were 10 years ago.”
  - ▶ Strongly Agree = 58 (19.7%)
  - ▶ **Agree = 91 (31.0%)**
  - ▶ **Neither Agree nor Disagree = 91 (31.0%)**
  - ▶ Disagree = 44 (15.0%)
  - ▶ Strongly Disagree = 10 (3.4%)

- ❖ “Clinical trials require more work than they did 10 years ago.”
  - ▶ **Strongly Agree = 124 (42.2%)**
  - ▶ **Agree = 124 (42.2%)**
  - ▶ Neither Agree nor Disagree = 41 (13.9%)
  - ▶ Disagree = 5 (1.7%)
  - ▶ Strongly Disagree = 0 (0.0%)
  
- ❖ “It is important for those working in the clinical trials industry to understand the “big picture” or “higher purpose” associated with their work.”
  - ▶ **Strongly Agree = 120 (41.1%)**
  - ▶ **Agree = 157 (53.8%)**
  - ▶ Neither Agree nor Disagree = 12 (4.1%)
  - ▶ Disagree = 2 (0.7%)
  - ▶ Strongly Disagree = 1 (0.3%)
  
- ❖ “Understanding the “big picture” or “higher purpose” of clinical trials makes the labor that goes into clinical trials more acceptable.”
  - ▶ Strongly Agree = 61 (20.7%)
  - ▶ **Agree = 145 (49.3%)**
  - ▶ Neither Agree nor Disagree = 60 (20.4%)
  - ▶ Disagree = 25 (8.5%)
  - ▶ Strongly Disagree = 3 (1.0%)
  
- ❖ “In general, pharmaceutical companies do not provide enough information about the progress of investigational drugs to sites who conducted research for them.”
  - ▶ Strongly Agree = 31 (10.6%)
  - ▶ **Agree = 111 (37.9%)**
  - ▶ Neither Agree nor Disagree = 70 (23.9%)
  - ▶ Disagree = 73 (24.9%)
  - ▶ Strongly Disagree = 8 (2.7%)
  
- ❖ “In general, pharmaceutical companies do not provide enough information about the progress of investigational drugs to patient-subjects who volunteered for studies.”
  - ▶ Strongly Agree = 51 (17.6%)
  - ▶ **Agree = 122 (42.1%)**
  - ▶ Neither Agree nor Disagree = 65 (22.4%)
  - ▶ Disagree = 46 (15.9%)
  - ▶ Strongly Disagree = 6 (2.1%)