

1. Background

The pharmaceutical industry supports almost 75% of clinical trials in medicine in the United States and the number of investigator sponsored studies (ISS) has been on the rise.^{1, 2} To help improve the number of studies that result in manuscripts and to generate more scientific literature, companies are focusing on strategies to identify which investigators and proposals to provide support for.

A company will often evaluate an investigator based on their experience level and number of ISSs, but little research has been done to show if these characteristics currently result in increased publications. Additionally, companies evaluate supported projects' abilities to be completed on time and within budget, but the success rate is variable and it is unknown if these studies are ultimately more likely to become published. A recent trend to help improve study completion rates is payment by milestones as opposed to lump sums.² Additional milestones for study publications are also frequently used, but this has not been proven to increase the number of published works. Previously, research has been done to survey companies on ISSs and publication rates, but there is little known from the investigator perspective.

2. Objectives

- To gain current knowledge of the experience levels of investigators and percentages of on time and within budget study completion rates
- To determine if investigator experience levels and on time study completion rates are associated with higher publication rates
- To determine if certain budgeting and funding strategies are associated with a high percentage of study publication rates

3. Methods

- A 17 question voluntary web-based and anonymous SurveyMonkey questionnaire was emailed to 486 recipients in January 2014 and fielded for three weeks
- Responses were recorded as close ended yes/no questions, or the investigator was asked to comment on how often an event occurred using pre-determined percentages and a 5 point Likert scale
- Statistical analyses and figures were created using Microsoft Excel 2010
- This project was reviewed by the Rutgers University IRB and was granted exempt review

4. Results

- There were a total of 48 responses (~10% responses rate)
- The majority of investigators (87.5%) came from an academic institution, while the remaining were in non-academic or private practice
- The investigators had varying degrees of years in practice:

0-5 Years (17%)	6-10 Years (36.2%)
11-19 Years (27.7%)	20+ Years (19.1%)

- The top 4 therapeutic areas investigators practiced in were:

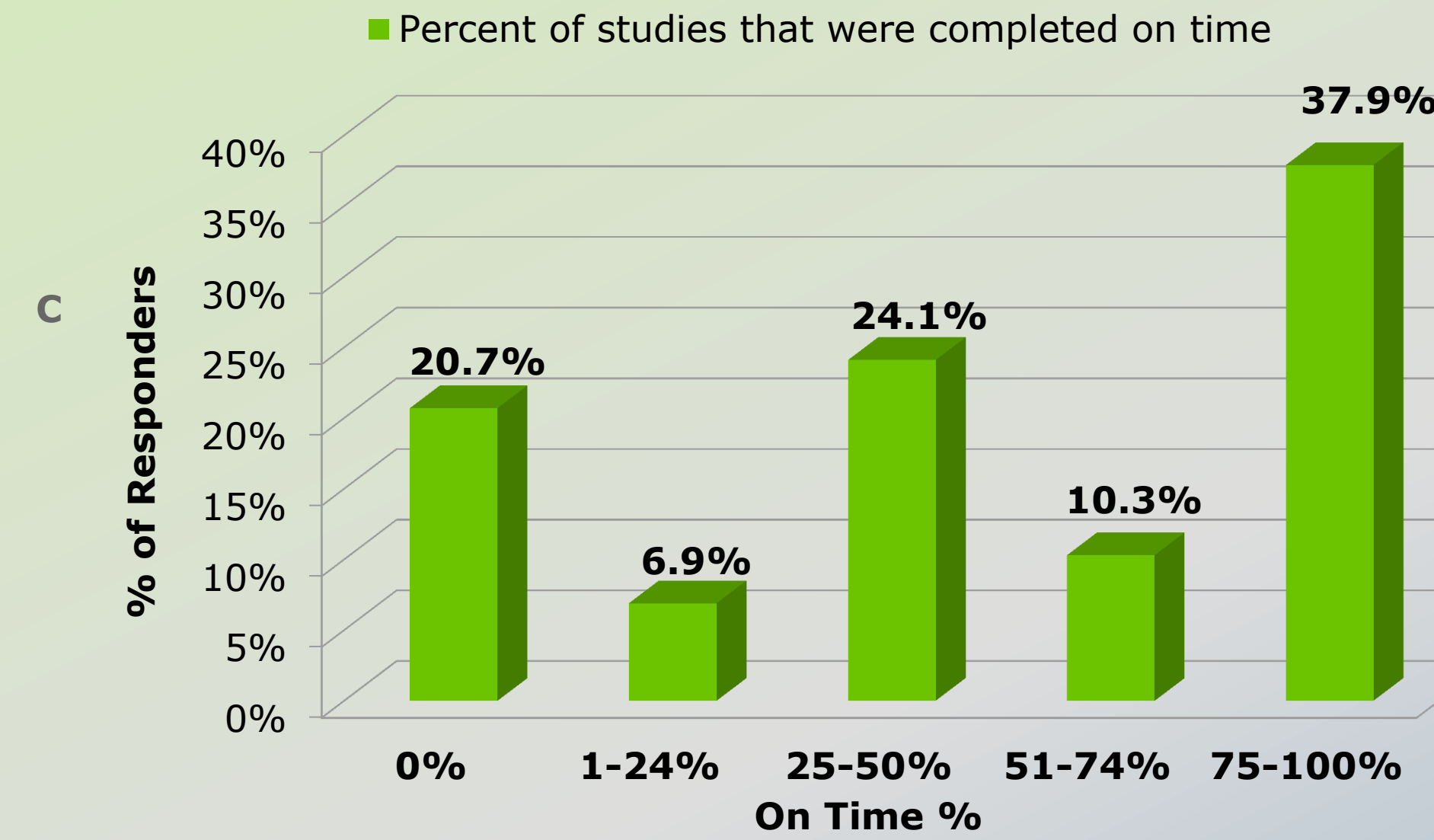
Oncology (43.2%)	Hematology (20.5%)
Women's Health (25.0%)	Endocrinology (11.4%)

Results (continued)

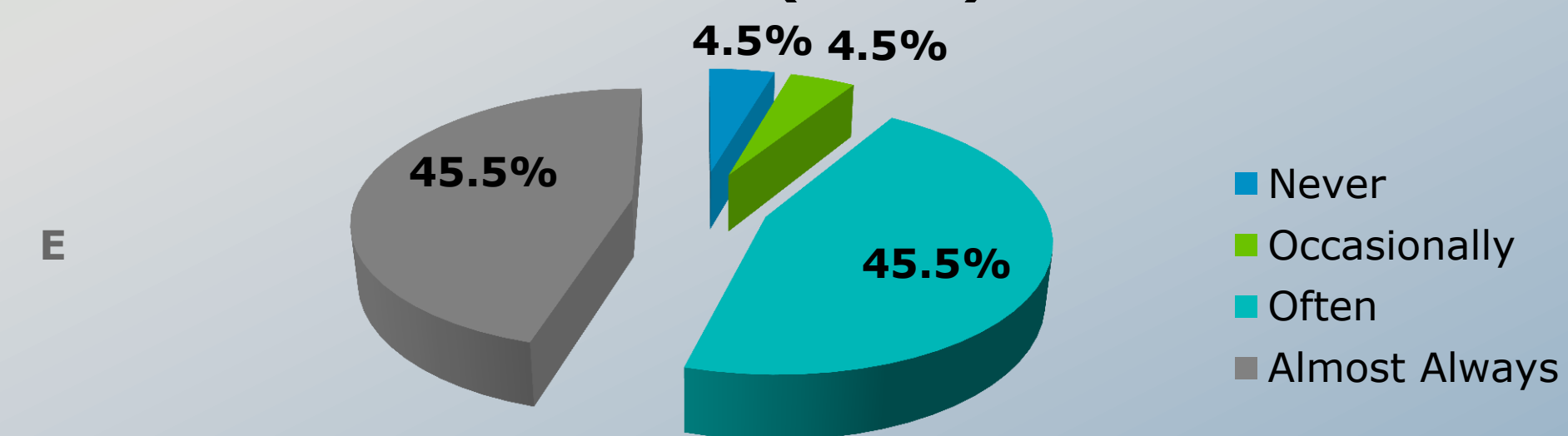
Number of Studies Completed By Years in Practice (n=47)

Years in Practice	0 Studies	1-2 Studies	3-5 Studies	6+ Studies
0-5	3 (27.3%)	4 (19.0%)	0 (0.0%)	1 (12.5%)
6-10	3 (27.3%)	12 (57.1%)	2 (28.6%)	0 (0.0%)
11-19	3 (27.3%)	4 (19.0%)	2 (28.6%)	4 (50%)
20+	2 (18.2%)	1 (4.8%)	3 (42.9%)	3 (37.5%)

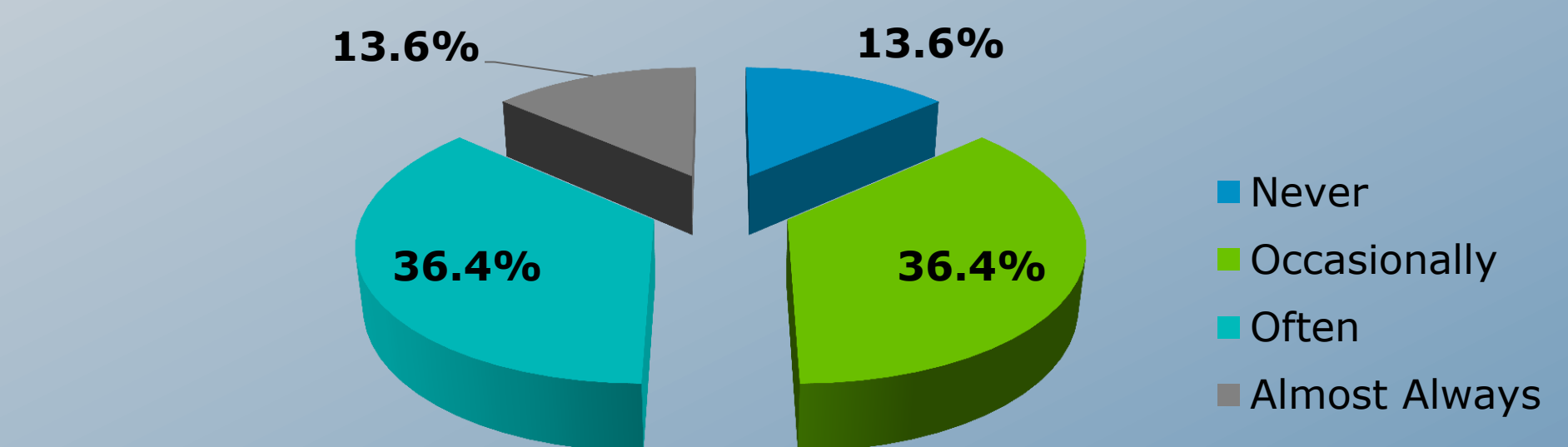
On Time Study Completion Rates (n=29)



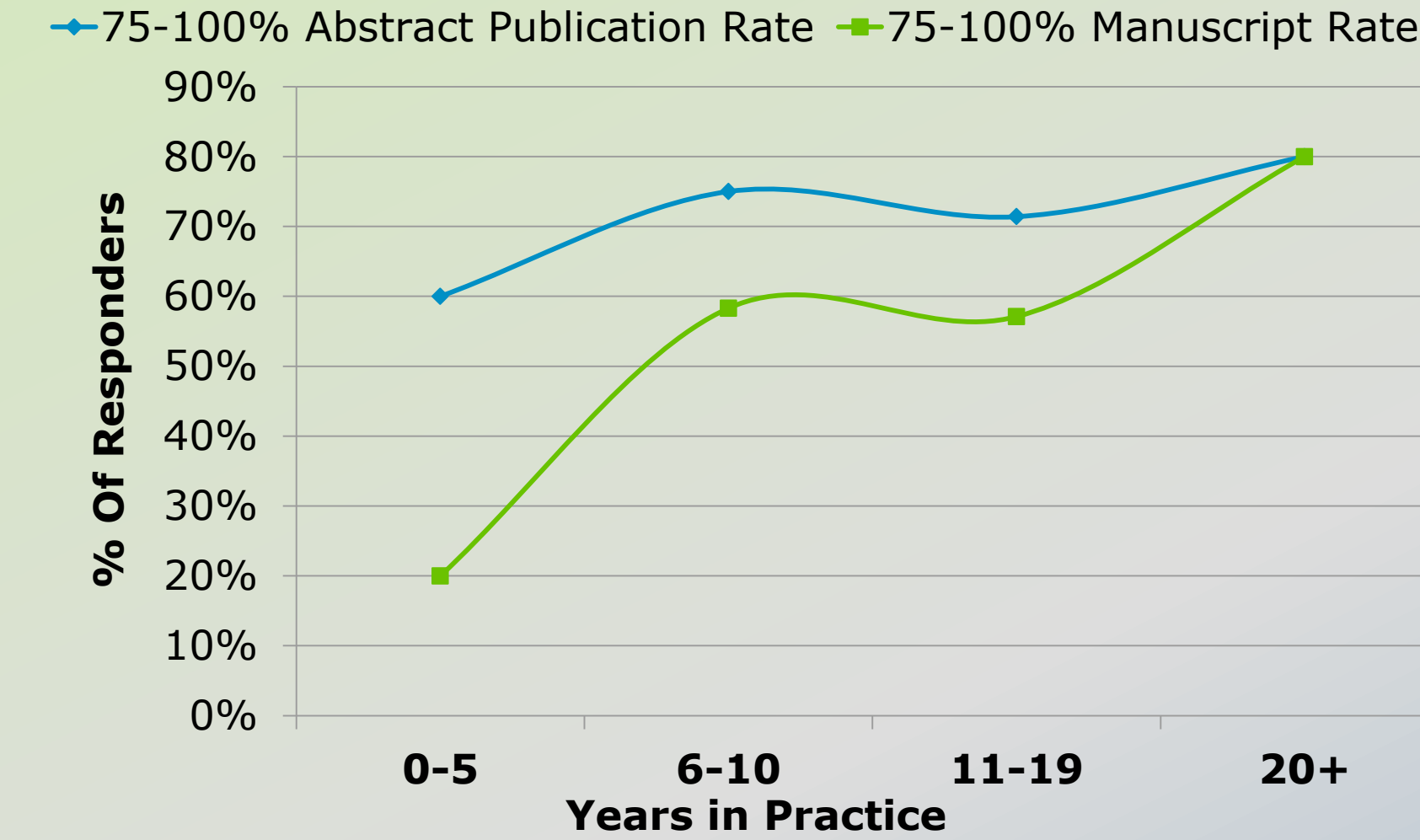
Are Milestone Funds Patient Based? (n=22)



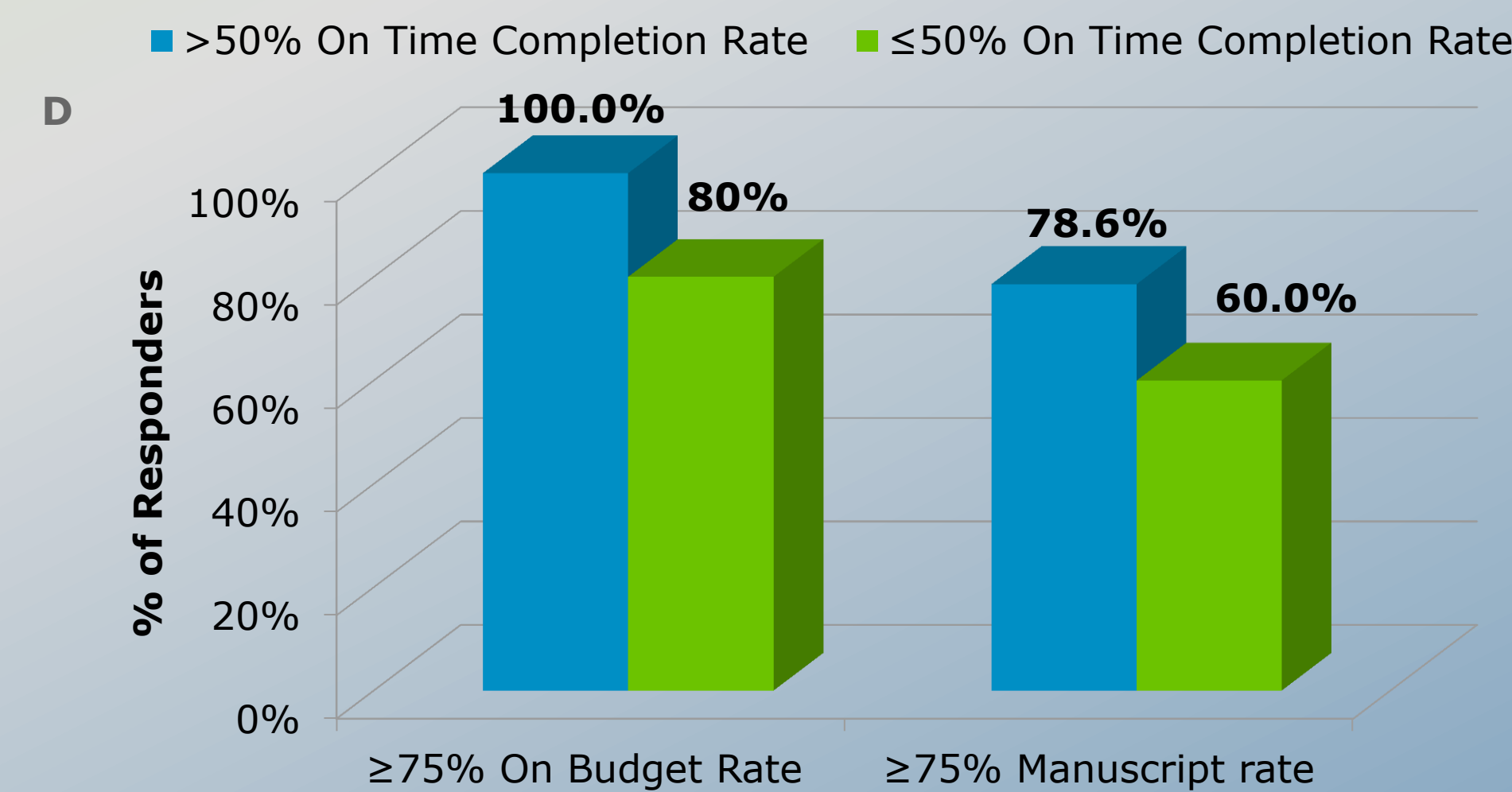
Are Milestone Funds Study Time Point Based? (n=22)



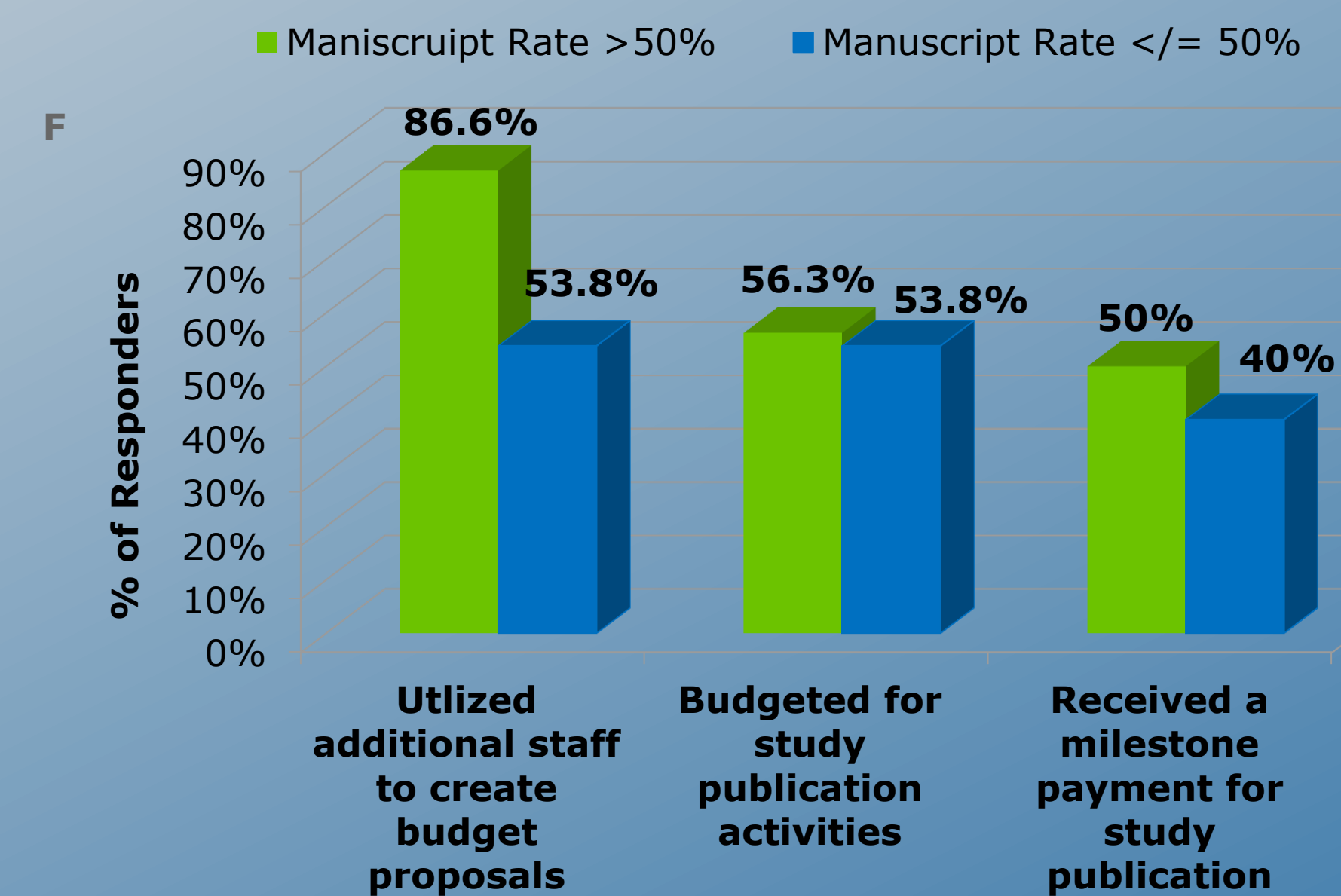
Study Publication Rates by Years in Practice



Budgeting and Publication Rates Based on On Time Completion Rates



Study Factors by Publication Rate (n=29)



Results (continued)

- All investigators who completed 3+ ISS were from an academic institution
- 82.8% of studies were completed within budget, but only 37.9% were completed on time
- More than half (55.2%) budget for study publication activities, but only 6.9% budget for a separate medical writer
- 70% of all studies resulted in a published abstract, while 53.3% resulted in a published manuscript
- 75% of investigators reported study funds were distributed by milestone payments, however the remaining 25% still received a lump sum
- Of the investigators that received milestone payments, 54.5% reported they do not receive a separate milestone for study publications

5. Discussion

The results of this survey are consistent with previous research conducted via surveying pharmaceutical companies, who report between a 50-80% ISS publication rate.² Gathering current metrics on ISSs can allow for both companies and investigators to benchmark themselves and can be used to further research into strategies for higher publication rates. If both industry and investigators can better understand the approaches that make an ISS successful, they can modify their processes to better increase their chances at publishing and generating scientific literature

- Limitations: All responses were self-reported. 43% of investigators had only completed 1-2 studies in the past 5 years so these percentages may appear more significant than others. 23% of investigators did not complete any ISS research within the past 5 years and were not eligible to complete ISS related questions, which had decreased the total number of completed responses.

6. Conclusions

- Investigators with the greatest years in practice had the highest number of ISSs and publications completed within the past 5 years.
- Some firms suggest that including milestones for manuscripts is the "best practice" for increasing study publication and this initial research suggests that this may be the case, but additional studies should be done to further justify this milestone.
- Results from this initial study do show that completing a study on time is more likely to be within budget and with a higher manuscript rate compared to those who investigators are delayed in their study activities.
- The results of this study reinforce the importance of dedicated resources to ensure that milestones are met and ISSs are completed on time

7. References

- Bodenheimer, T. 2000. Uneasy alliance: Clinical investigators and the pharmaceutical industry. *New England Journal of Medicine* 342:1539-1544.
- Cutting Edge. www.cuttingedgeinfo.com/2011/investigator-initiated-trials-medical-publications

