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National Institutes of Health



National Institutes of Health Commercialization Assistance Program
(NIH-CAP)

NIH-CAP 2005-06

Baseline Tracking Report

for the period

September 1, 2005-June 30, 2006

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Background & Introduction

Larta tracks the progress of NIH-CAP participating companies for an 18 month period in two 9 month intervals, including a baseline period, which spans the duration of the program. This report provides progress tracking results for the companies that participated in the CAP in 2005-06, for the baseline period September 1, 2005- June 30, 2006. This report presents only a summary of the data. Detailed source data can be found in a separate excel file (Processed Tracking 2005-06 Companies Baseline.xls). We discuss first the overall commercialization progress, and then separately evaluate direct CAP impact.

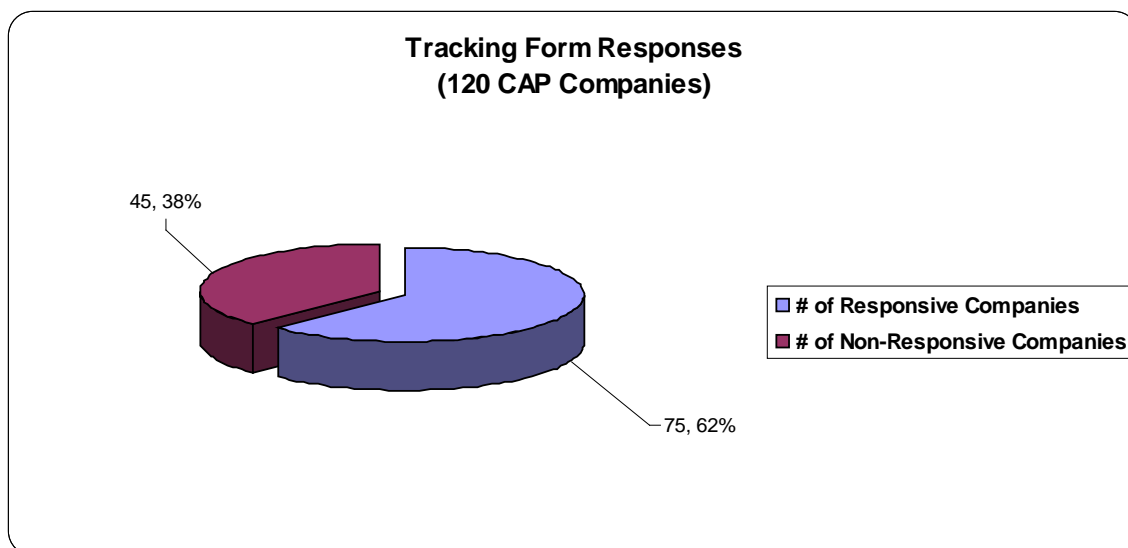
The Tracking Form

The second year of the CAP for NIH SBIR Phase II grantees was launched in July 2005. 107 companies completed the program in June 2006; 4 companies completed prior to the official program end date; and 18 companies did not complete the program of which 11 participated for a sufficient time period to be tracked. Thus, at the end of the program, 122 companies were sent baseline tracking forms. For this baseline interval, 2 companies were relieved from tracking (see Appendix A), leaving 120 companies to be tracked. Some notable features of the tracking form (see Appendix B) are listed below:

- Tracking is focused on quantifiable end results, i.e., deals, revenue growth, increased equity investment, increased employment, M&A outcomes.
- In addition, the form defined a “deal activity pipeline”. We hope that this attempt at quantifying complex and often circuitous commercialization efforts will provide some predictive capabilities in the future, somewhat analogous to sales pipeline forecasting.
- Participants were asked to report separately their overall commercialization progress and their evaluation of the CAP impact. Data on companies’ commercialization progress are in principle objective and could be used in the studies of SBIR program performance in general; their use in evaluating CAP itself is limited due to the lack of a control group of SBIR companies.
- Data on CAP impact are indicative of CAP significance. Companies rated the CAP impact as 1) Major, 2) Valuable, 3) Minor or 4) None. For purposes of measuring CAP impact, Valuable and Minor impact are determined in this report to be ‘Some’ impact on the companies.
- Finally, with the question on revenue, the largest source of revenue was solicited from companies and for them to explicitly state commercial revenue vs. revenue from R&D grants and contracts.

Response Rate

On September 13, 2006, 122 of the 2005-06 NIH-CAP companies were sent the tracking form from Kay Etzler at NIH and 2 were later exempt from tracking. 75 of the resulting 120 companies responded to the tracking request, after several e mail reminders and follow-up via telephone; a 63% response rate. The response rate of 63% is lower than that in the baseline period for the 2004-05 CAP companies. We believe this is because the reminder and follow-up effort was not as extensive as that conducted for the 2004-05 companies. This issue will be addressed with NIH and next steps outlined. On the positive side, the quality of responses was better with fewer NA entries.



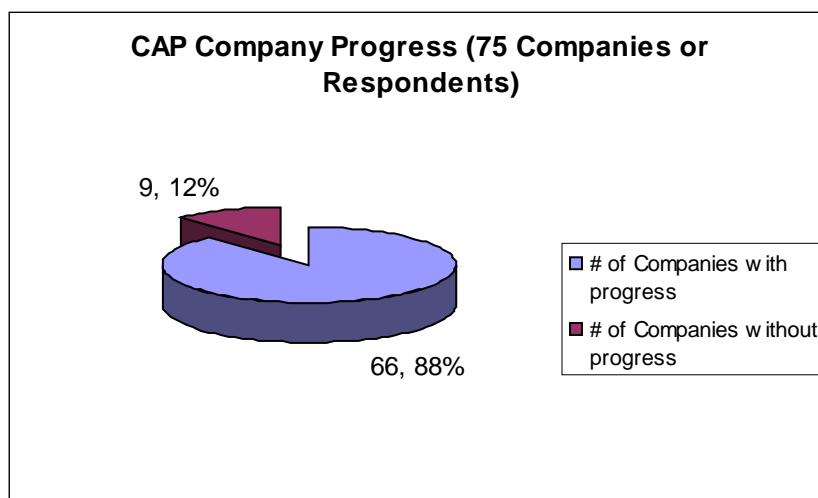
Commercialization Progress

The following charts describe the progress (with the commercialization of SBIR Phase II technologies) that the companies have made during the first interval since the culmination of the CAP. Progress is determined by a positive change in the following categories:

- Activity in Partnerships and Deals
- Growth of Revenue
- Growth of Equity Investment
- Growth of Employment
- Acquisitions

Activity in Partnerships and Deals

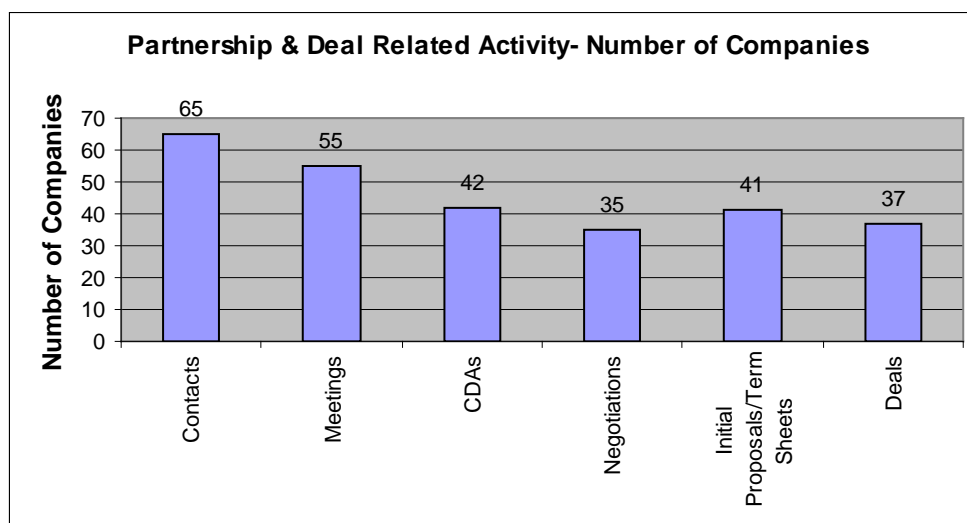
The chart below outlines commercialization progress with respect to partnership and deal related activities, excluding the companies that were non-responsive to the tracking request. Out of the 75 companies that responded to the baseline tracking request, an encouraging 66 companies or 88% of the companies indicate commercialization progress in the partnership and deal related activities area. This 88% rate is higher than the 81% rate from the baseline results of the 2004-05 CAP companies.

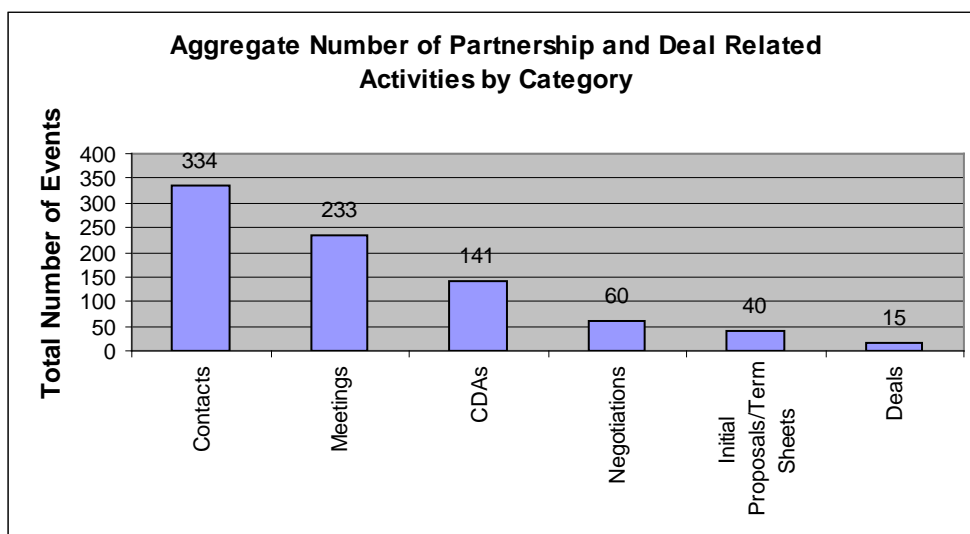


Note that “Progress” is defined as at least one event in at least one of the partnership and deal related activities listed below:

1. Contacts with Investors and Partners
2. Meetings with Investors and Partners
3. CDAs signed
4. Negotiations with Investors and Partners
5. Initial Proposals and Term Sheets
6. Deals

The charts below indicate the number of companies engaged in multiple partnership and deal related activities and the aggregate number of partnership and deal related activities by category.



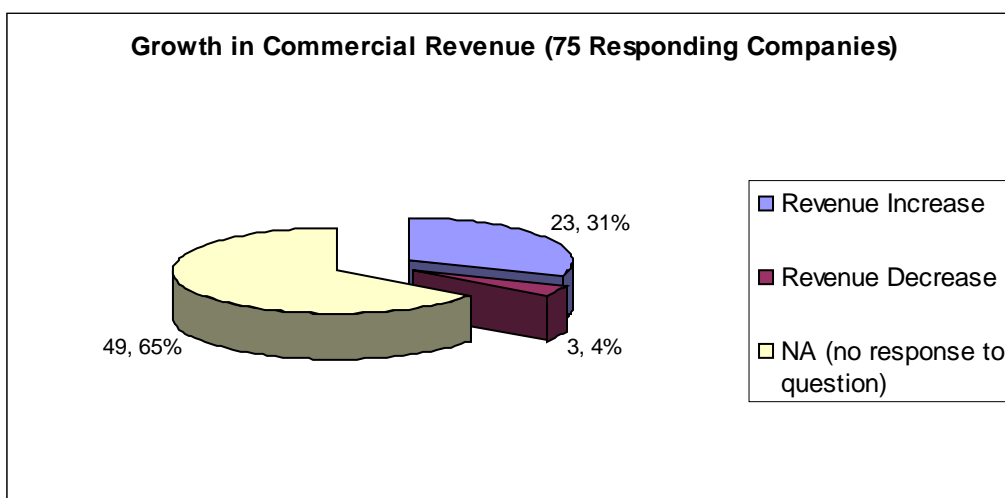


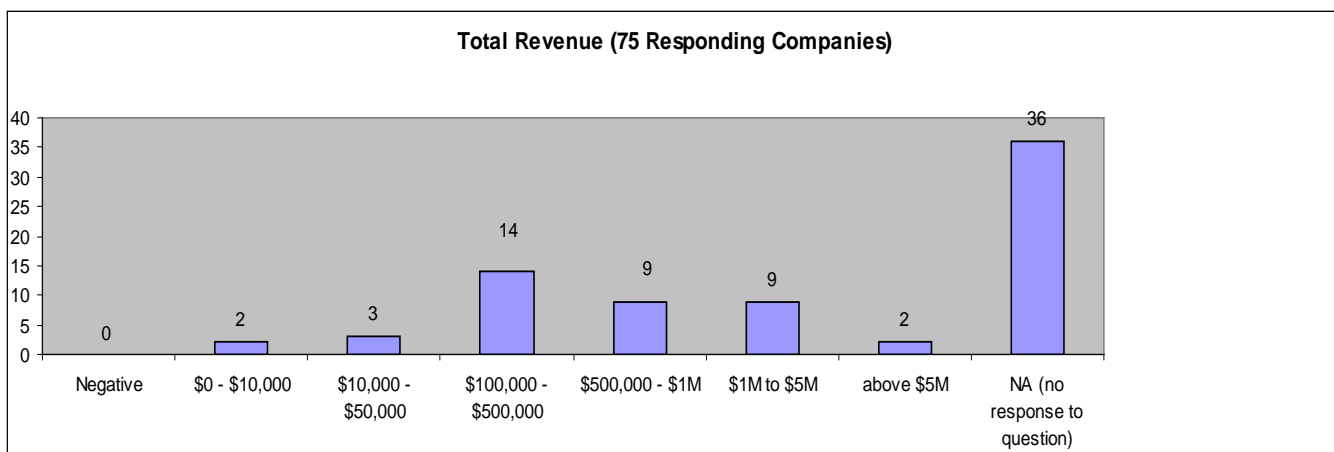
Key observations:

- Patterns in partnership and deal related activities are similar to that of the baseline results of the 2004-05 companies, but slightly heavier in the later stages of partnership and deal related activities.
- The number of deals for the 2005-06 companies during the baseline period came in slightly lower at 15, compared with 23 for the 2004-05 companies during the baseline period.

Growth in Commercial Revenue

Note that the growth in commercial revenue refers to the change in total company revenue rather than the revenue based on the CAP technology. This approach was taken in anticipation of the reluctance of companies to provide detailed revenue data.

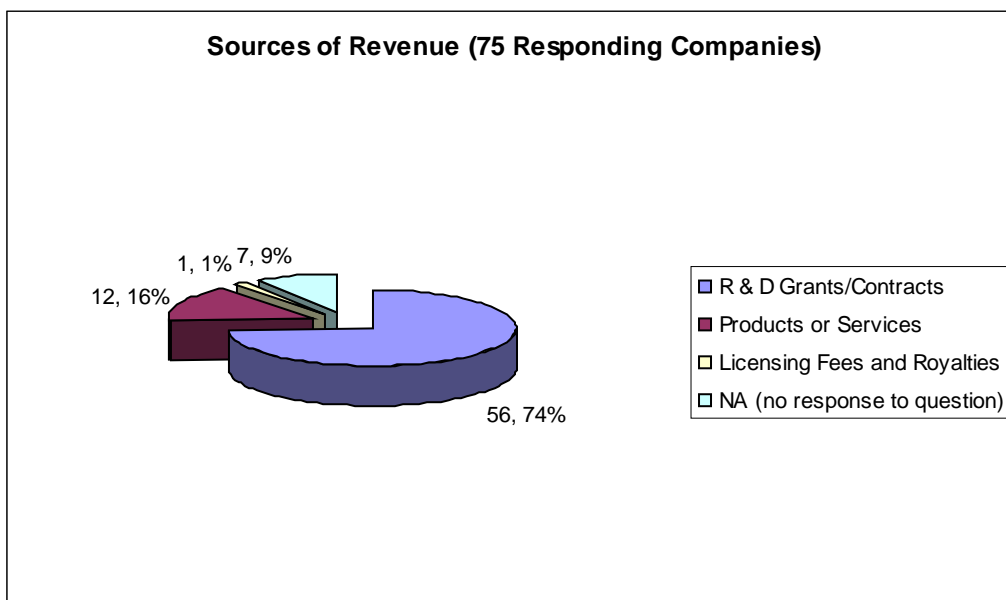




Key observations:

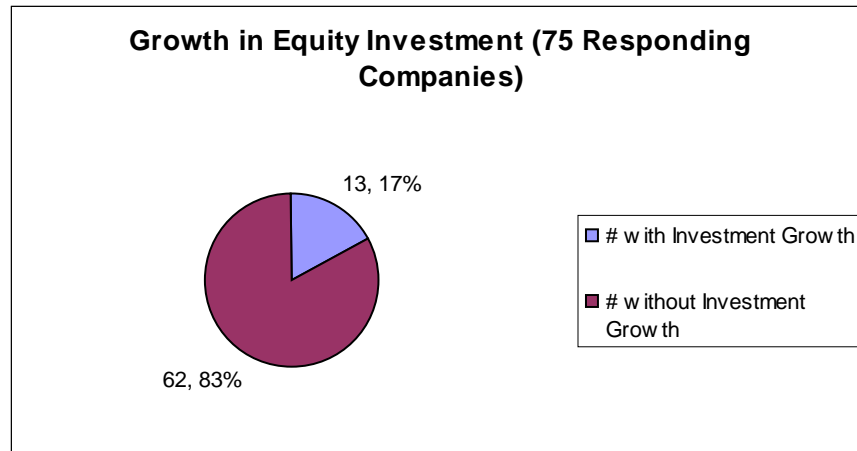
- 31% of companies for the 2005-06 baseline period indicated a revenue increase compared with 40% for the 2004-05 baseline period.
- None of the companies have reported a decrease in revenue.
- Total revenue was not determined for the 2004-05 baseline period, therefore a comparison is made here with the 2004-05 first interval of progress tracking. On comparing 2005-06 results to the 2004-05 first interval, similar patterns of total revenue are observed.
- 2 companies have reported revenue over \$5 million and 9 between \$ 1 million and \$5 million.
- The highest level of total revenue was \$17 million reported by [REDACTED] followed by \$13 million reported by [REDACTED].

However, R&D Grants/Contracts remain the largest source of total revenue for 74% of companies, as shown below. Sources of revenue were not determined for the 2004-05 baseline period, therefore a comparison is made here with the 2004-05 first interval of progress tracking. It appears that the R&D grants have increased relatively to commercial revenue for the 2005-06 baseline period when compared to results from the 2004-05 first interval of progress tracking.

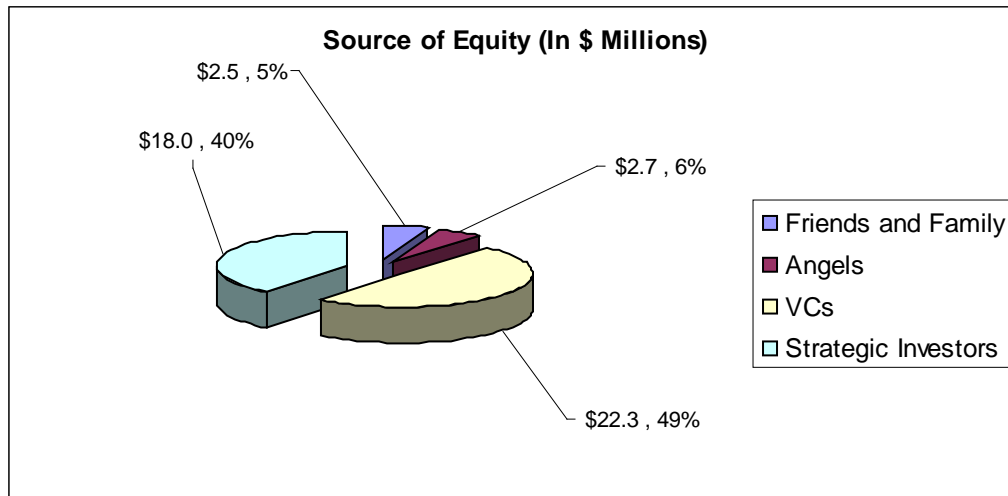


Growth in Equity Funding

The data, of course, refer to the growth of the equity funding for the company as a whole. 13 companies or 17% indicated an increase in equity funding and from one or more sources of equity funding. This is compared with a rate of 20% for the 2004-05 baseline period.



The total amount of new funding by source of funding is shown below.



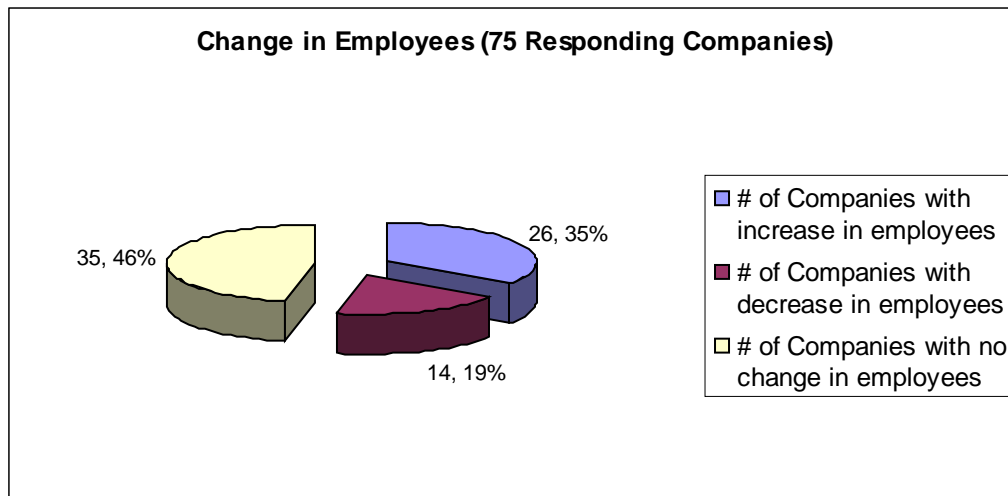
Key observations:

- VC funding accounted for the largest source of equity funding. Angels were the dominant source of funding last year.
- In total, \$45.6 million was raised by the 13 CAP companies that were successful with equity investment. Total equity investment was three times greater during the 2005-06 baseline period compared with the \$15 million raised during the 2004-05 baseline period.
- The bulk of funding went to [REDACTED] (\$22 million in VC funding), and [REDACTED] (\$17 million from [REDACTED]). While both companies do not credit the CAP for this investment, the aggregate CAP impact on equity investment has increased in the 2005-06 baseline period compared with the 2004-05 baseline period (see CAP impact on equity investment).

Other Success Indicators

Employees

26 companies or 35% of the respondents indicated an increase in the number of employees. This is lower than the 41% rate observed in the 2004-05 first interval progress tracking.



The responses also indicated that the aggregate gain in employment was negative (-8) for this period compared with a 79 gain in the 2004-05 baseline period and 138 gain in the 2004-05 first interval.

Mergers & Acquisitions

No mergers and acquisitions were reported in the baseline interval since the culmination of the 2005-06 CAP.

CAP Impact

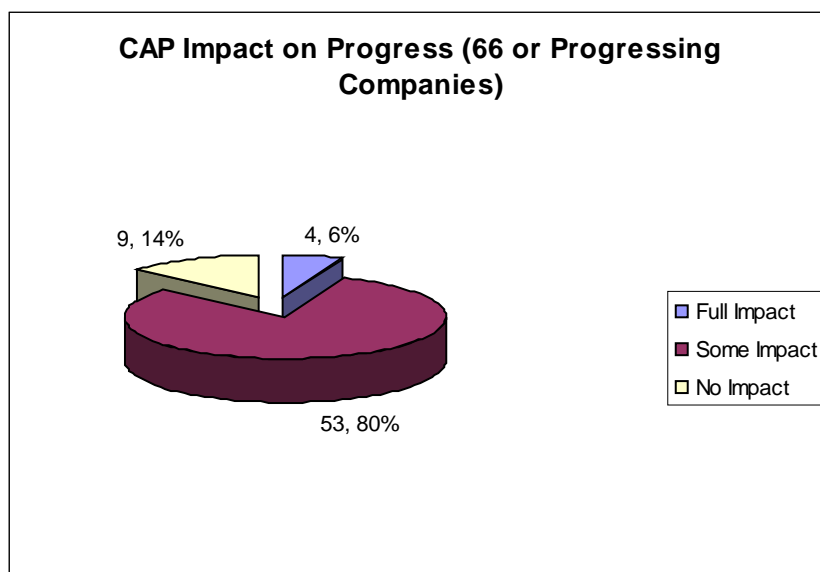
CAP Impact was rated by the companies as either 1) Major, 2) Valuable, 3) Minor or 4) No Impact. CAP impact was determined for the following activities that have been addressed earlier in the report (Note that Valuable and Minor impact are determined in this report to be 'Some' impact on the companies).

- Activity in Partnerships and Deals
- Growth in Revenue
- Growth in Equity Investment

Note that the data here represent companies' subjective assessments on the impact of CAP on specific commercialization outcomes. Companies have separately outlined their feedback on the CAP, the results of which have been submitted to NIH.

Activity in Partnerships and Deals

Progress is defined as at least one activity in at least one of the partnership and deal related activity categories.



Key observations:

- 4 companies have attributed the CAP with major impact and 53 companies have attributed the CAP with some impact.
- 86% of the progressing companies have attributed major or some impact to the CAP on partnership and deal related activities, compared with 66% for the 2004-05 baseline period, a significant increase!

Comments from CAP participants regarding CAP impact on partnerships and financing deals are shown below. Note that these are comments from companies that attributed the CAP with major or some impact.

"In the interval from the Showcase to now, I have had a series of discussions with large companies, but none are completed. I hope to move them forward this month, but all needed "several months" for internal review of materials supplied to them. Companies include [redacted] [identified via the showcase], and [redacted] and [redacted] [identified via my sources]. Plans are to push for essential meetings after that period."

"[redacted] we met at the Larta conference; NDA exchanged, negotiations for possible partnership ongoing."

"The CAP program introduced [redacted] to the concept of value added by a [redacted]. This concept has changed the company's approach to new product ideas in that we first look for partners where our technology can be merged with their existing product lines to provide mutual value."

"In licensing due diligence stage with Company #1; signed an MOU with Company #2; formed informal partnership with Company #3."

"Confirmed that a strategic partner is more appropriate than venture investment at this stage in our company, and gave us a methodology and timeline for approaching such partners, through development of the business case."

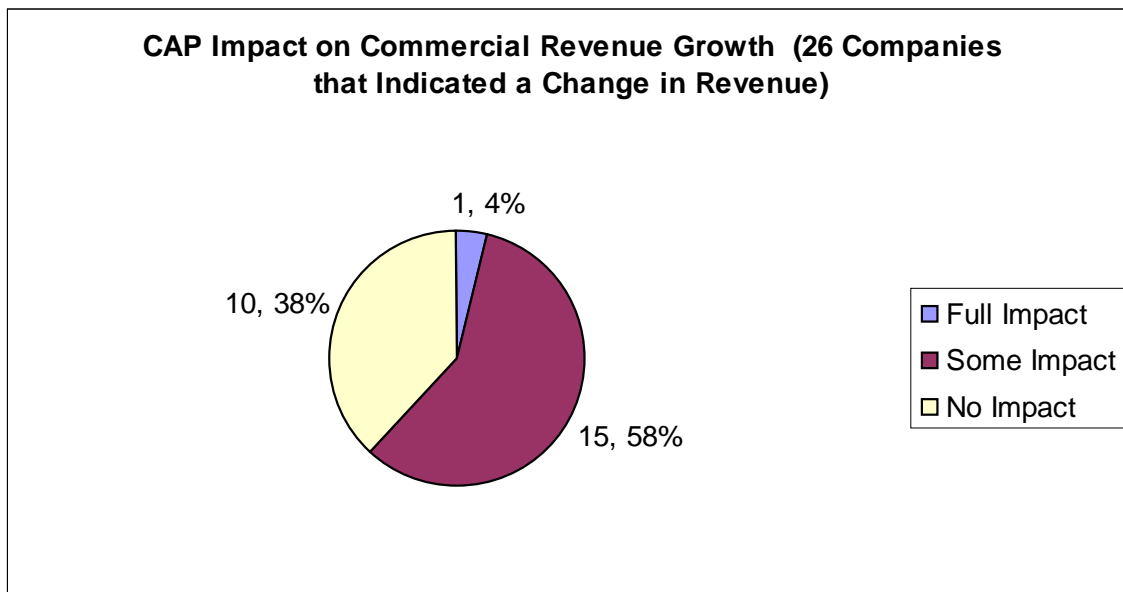
"The CAP program has a positive impact in attracting prospective investors/partners."

“The CAP served as a valuable educational program, resulting in a more considered and thoughtful positioning. An impactful outcome is not likely to be seen for 1 – 2 years, by which time [REDACTED] will be fully implementing the business strategy developed in CAP.”

“CAP helped [REDACTED] prepare the presentation materials to attract potential investors and partners.”

“The NIH CAP program has helped focus our strategic plan. During the next year, as we complete the SBIR Phase II development, we are prepared to become more aggressive in our contacts and meetings.”

Growth in Revenue



The above chart shows the impact that CAP had on the companies' revenue growth. Note that some companies commented that it is still too early to assess CAP impact on revenue.

Key observations:

- 62% of the 26 companies that indicated a change in revenue have attributed major or some impact to the CAP, compared with 28% for the 2004-05 baseline period, a significant increase!
- [REDACTED] found the CAP to have a full impact on its revenue growth stating, “We are in a major shift of the company this year into manufacturing and sales. Sales should equal about 30% of our gross income in 2006, and will be triple the amount of sales in 2005. CAP has helped us focus on changing the direction of the company.”

Comments from CAP companies that felt that it was early to determine the impact of CAP on revenue are shown below:

“Too early to access impact of the CAP.”

“This is a new company and our first product and it is still too soon to tell what impact CAP will have on revenue.”

“As described in our commercialization plan, we expect no commercial revenues until the second half of 2007.”

Other comments include:

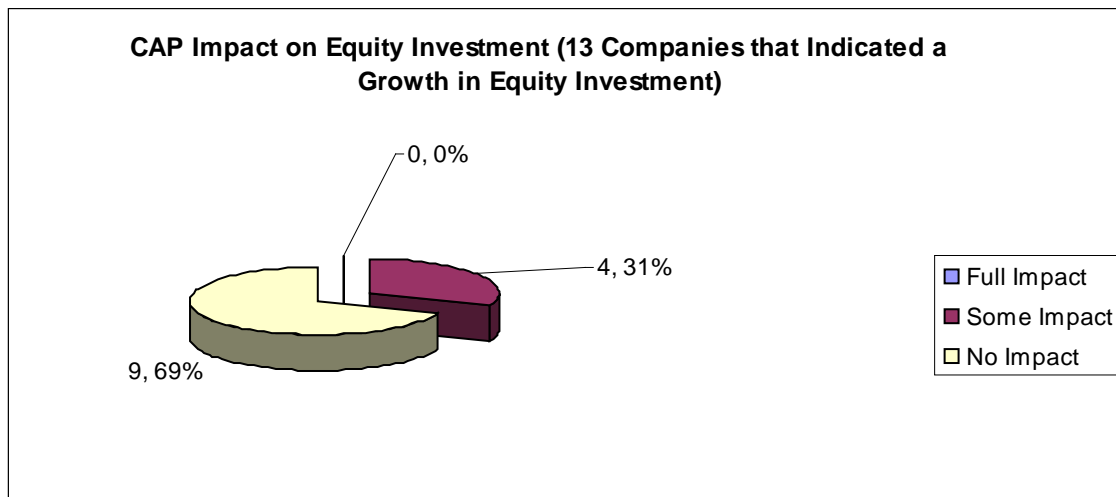
"We have recently acquired new customers partly due to the business strategy we gained from the CAP program. This has increased our opportunities to keep our cash flow consistent, which helps us continue the pursuit of commercializing the Phase II work."

"Seeds are sown and \$2.6 million will be reported in the next time period."

"Our grant income is unchanged from last year. Sales of the product have been solely in our Arizona test market. Significant changes in revenue are expected in Q2 of 2007."

"Most of revenue comes from grants. Three institutions have expressed interest in working together to meet their needs with [REDACTED] products & services. Meetings took place after June 2006 and will be reported in next Larta update."

Growth in Equity Funding



The above chart shows the impact that CAP had on the companies' growth in equity investment.

Key observations:

- 31% of the 13 companies that indicated a growth in equity investment attributed the CAP with some impact compared with 17% for the 2004-05 baseline period, once again a significant improvement!
- Although [REDACTED] and [REDACTED] garnered the bulk of equity investment [REDACTED], it is apparent from the 31% CAP impact rate that the bulk of CAP impact was on companies with lesser levels of investment and not the companies that received the highest levels.

Comments from these companies that attributed the CAP with some impact include:

"An equity investment in the company has been offered by an investment firm and currently in a negotiation stage. The CAP has valuable impact in attracting this interest."

"The NIH-Larta program has been extremely helpful from a strategic and tactic perspective. We are better prepared to formulate and present an attractive medical technology opportunity to investors."

"I believe we will ultimately seek private investment from a large investment group.

We have an existing business relationship with them and they have expressed interest in the technology. The NIH-Larta program will allow us to advance the technology strategically and to increase the value of the company."

"We will approach investors during the next few months, while we complete this Phase II. It is in our best interest to achieve another technology milestone, which will increase (double) sales beyond the current success."

Some companies were not looking for equity investment and had the following comments:

"██████████ is not pursuing capital investment at this time."

"This was not one of our goals – the software production is funded entirely through sales."

"At this time, ██████████ does not have enough Products or Technology advantage for the Angels or VCs or Strategic Investors for the Equity Investment in ██████████."

Summary

Overall, the 2005-06 baseline results indicate that the NIH-CAP 2005-06 was successful in its commercialization efforts with significant CAP impact recorded on partnering and deal related activities, revenue, and equity investment. Similar patterns emerged in the 2005-06 baseline period when compared with the 2004-05 baseline period, especially in the case of partnering and deal related activities. 15 companies reporting a deal is encouraging, as well as the aggregate change in revenue reported for this interval or \$28.7 million (total revenue stood at \$57 million). The amount of equity funding for this period (\$45.6 million) was three times more than that in the 2004-05 baseline period (\$15 million), with the CAP mostly impacting companies that did not receive the highest levels of funding during the tracking period. The aggregate change in employment was negative compared with a positive rate of 79 in the 2004-05 baseline period.

Key results are summarized below:

	2005-06 Baseline	2004-05 Baseline
Aggregate Change in Revenue	\$28.7 Million	NA
CAP Impact	62%	28%
New Equity Investment	\$45.6 Million	\$15 Million
CAP Impact	31%	17%
Employment Growth	(8)	79

The first interval progress tracking for the 2005-06 CAP companies will be conducted in April 2007 for the period July 1, 2006- March 31, 2007.

APPENDIX A

2005-06 CAP companies relieved from tracking:

Company Name	Notes
[REDACTED]	Only being tracked for 2004-05 participation as company withdrew from the 2005-06 program too early for progress tracking
[REDACTED]	[REDACTED], CEO and CAP leader passed away. Since [REDACTED] CAP participation was solo and no one else was familiar with his CAP progress, the company is not able to provide the commercialization data we have requested on the tracking forms.

APPENDIX B

NIH-CAP 2005/2006
COMMERCIALIZATION PROGRESS TRACKING FORM- BASELINE
September 1 2005-June 30 2006

PLEASE RETURN BY OCTOBER 16, 2006 TO KETZLER@LARTA.ORG

Company Name:
CAP SBIR Grant #:
Name of Individual Completing Form:
Position:
E-Mail:
Telephone:

Please fill in the **COMPANY COMMERCIALIZATION PROGRESS TRACKING** form below. NIH is very interested in your commercialization progress and if the CAP program was helpful. To start, we are looking for your inputs about your commercialization progress from September 1, 2005 until June 30, 2006 to serve as a base. At nine-month intervals (April 2007 and January 2008), you will receive similar forms in order to assess the long-term impact of the CAP. We also believe that such tracking can be beneficial to you as a management tool to periodically assess your company's progress and growth.

The tracking form is divided into four parts: (1) partnerships and financing deals, (2) revenue (3) equity investment, (4) and other success indicators (employees, acquisitions). It's difficult to measure the impact the CAP may have had on you progress, however, questions have been included to allow for your opinion to be expressed.

1. PARTNERSHIPS AND FINANCING DEALS

- a) As it relates to your CAP-related technology, please indicate your company's progress with respect to partnerships and financing deals. State the number of partnership and deal-related activities in which your company has engaged between September 1, 2005 until June 30, 2006. If you are pursuing both partnering and financing, add the numbers together.

	Number of Partnership and Deal Related Activities Your Company Has Engaged in Between September 1, 2005 and June 30, 2006	Describe Significant Outcomes
Contacts with Investors and Partners Count only contacts you had a meaningful conversation with about your mutual interests		
Meetings with Investors and Partners Meetings can be face-to-face or by phone/web but should involve exploration of potential deals in some detail.		

	Number of Partnership and Deal Related Activities Your Company Has Engaged in Between September 1, 2005 and June 30, 2006	Describe Significant Outcomes
Confidential Disclosure Agreements signed CDA (NDA) agreements are generally a pre-requisite for any serious discussion with potential partners. Investors generally do not sign CDAs.		
Negotiations with Investors and Partners At this stage, all parties are interested in the deal and you are exploring various give and take.		
Initial Proposals and Term Sheets These are binding proposals of key terms of the deal.		
Deals Signed legal documents and money in the bank. Please indicate the dollar amount of each deal.		

- b) Please indicate the impact of the CAP on your partnering and financing activities for the period September 1, 2005 to June 30, 2006.

___ Major Impact ___ Valuable Impact ___ Minor Impact ___ No Impact

Comments:

2. REVENUE

Please report the results for the whole company and not just your CAP-related technology. Do not include SBIR grants or other government contracts (except when asked about R&D Grants/Contracts in c) below).

- a) Please state the *cumulative change* in company revenue between September 1, 2005 to June 30, 2006.

_____ (\$millions)

- b) Please state the *total revenue* as of June 30, 2006

_____ (\$millions)

- c) Please indicate the largest source of revenue (Choose one)

R&D Grant/Contracts _____ Products or Services _____ Licensing Fees & Royalties _____

d) Please indicate the impact of the CAP on the change in company revenue for the period

September 1, 2005 to June 30, 2006.

____ Major Impact ____ Valuable Impact ____ Minor Impact ____ No Impact

Comments:

3. EQUITY INVESTMENT

a) Please state the total amount of equity investment received by the whole company INCLUDING your CAP-related technology in the time period September 1, 2005 to June 30, 2006.

	Amount of Equity Investment
Friends & Family	
Angels High net worth individuals; always invest as individuals although may belong to angel organizations.	
VCs Institutional investors	
Strategic Investors Investors that are looking to achieve other goals in addition to financial returns. Typically corporations seeking to fill or expand their product lines.	

b) Please indicate the impact of the CAP on equity investment received for the period

September 1, 2005 to June 30, 2006.

____ Major Impact ____ Valuable Impact ____ Minor Impact ____ No Impact

Comments:

4. OTHER SUCCESS INDICATORS (EMPLOYEES, ACQUISITIONS)

a) Have the number of employees in your company increased since September 1, 2005? If yes, please specify the number of employees in September 1, 2005, versus the current number of employees, and the titles/positions of the new employees.

	Employee Information
Number of Employees in September 1, 2005	
Current Number of Employees	

b) Has your company been acquired? Yes ____ No ____

If yes, NIH would like to continue tracking the progress of the SBIR-developed technology for the next 9 months , therefore please provide the following information.

	Acquisition Information
Name of the Acquiring Company	
Change in Company Name as a Result of the Acquisition	
Change in Company Contact Information as a Result of the Acquisition	
Additional Details	

THANK YOU ONCE AGAIN FOR YOUR PARTICIPATION IN THE 2004/2005 CAP AND FOR YOUR FEEDBACK. IT WAS A DELIGHT TO WORK WITH YOU AND WE WISH YOU THE BEST OF SUCCESS.