



U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health



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

NIH-CAP 2004-05

First Interval Tracking Report

for the period

July 1, 2005-March 31, 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, in addition to the baseline period, which spans the duration of the program. This report provides progress tracking results for the companies that participated in the CAP in 2004-05, for the first interval since the culmination of the CAP on July 1 2005-March 31, 2006. This set of companies was tracked for the baseline period of September 2004 to June 2005 as well and results have been previously submitted to NIH.

The Tracking Form

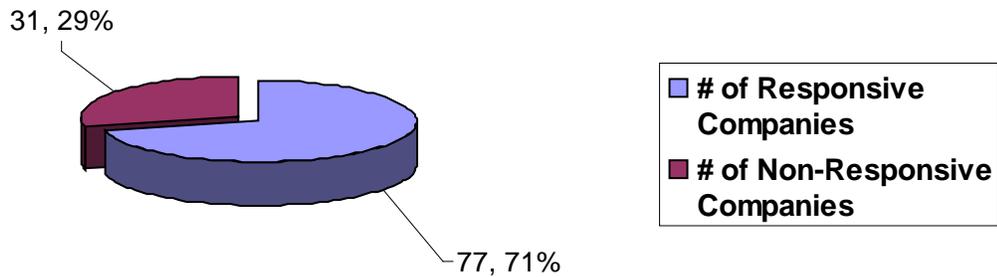
The first year of the CAP for NIH SBIR Phase II grantees was launched in July 2004. 114 companies completed the program in June 2005. At the end of the program, all 114 companies were sent baseline tracking forms. For the first interval, 6 companies were relieved from tracking (see Appendix A), leaving 108 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 the CAP impact are indicative of CAP significance. However, they are subjective estimates and cannot be relied upon for longer tracking periods. Note that for the first interval, companies were no longer expected to rate the CAP impact on a scale of 1 to 5, but to indicate if the CAP impact was 1) Major, 2) Valuable, 3) Minor or 4) None.

Response Rate

On April 3, 2006, 108 of the 114 2004-05 NIH-CP companies were sent the tracking form from Kay Etzler at NIH. 77 of the 108 companies responded to the tracking request, after several e mail reminders and follow-up via telephone; an encouraging 71% response rate. The response rate for the baseline period was 79%, so for the first interval, a response rate between 70% and 75% was more than satisfactory given that more time had elapsed since the culmination of the CAP.

Tracking Form Responses (108 CAP Companies)



This report presents only a summary of the data. Detailed source data can be found in a separate excel file (Processed Tracking 2004-05 First Interval.xls). We discuss first the overall commercialization progress, and then separately evaluate direct CAP impact.

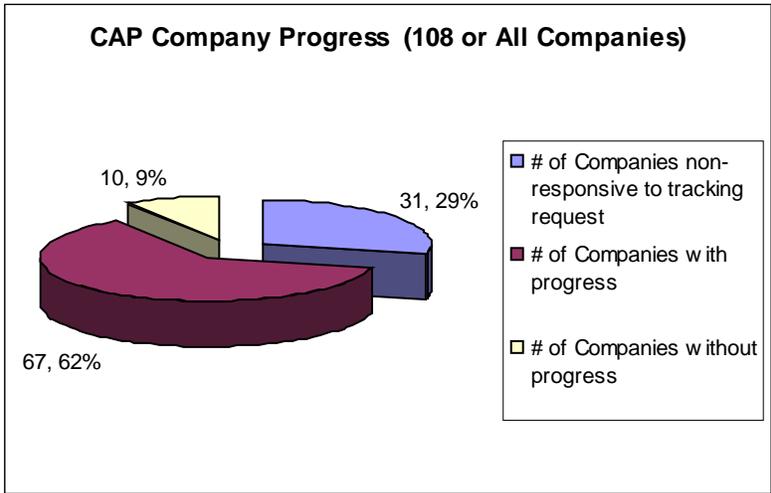
Commercialization Progress

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:

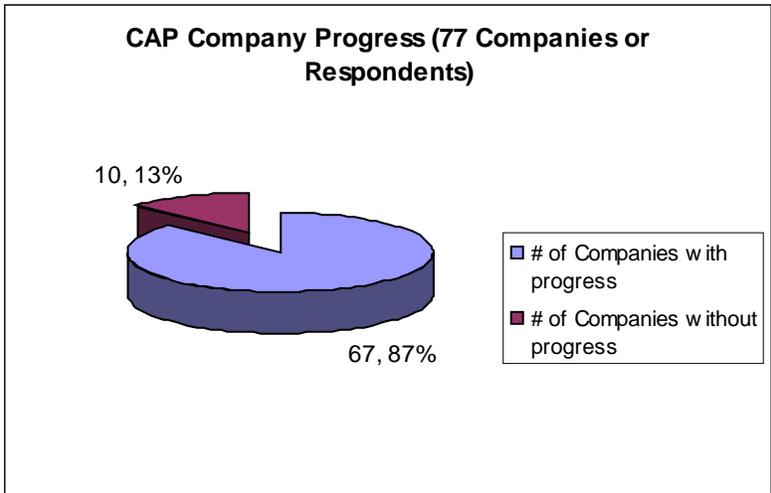
- Activity in Partnerships and Financing Deals
- Growth of Revenue
- Growth of Equity Investment
- Growth of Employment
- Acquisitions

Activity in Partnerships and Financing Deals

67 companies or 62% of all participants showed commercialization progress as shown in the graph below (compared with 73 companies or 64% in the baseline period when 114 companies were tracked).

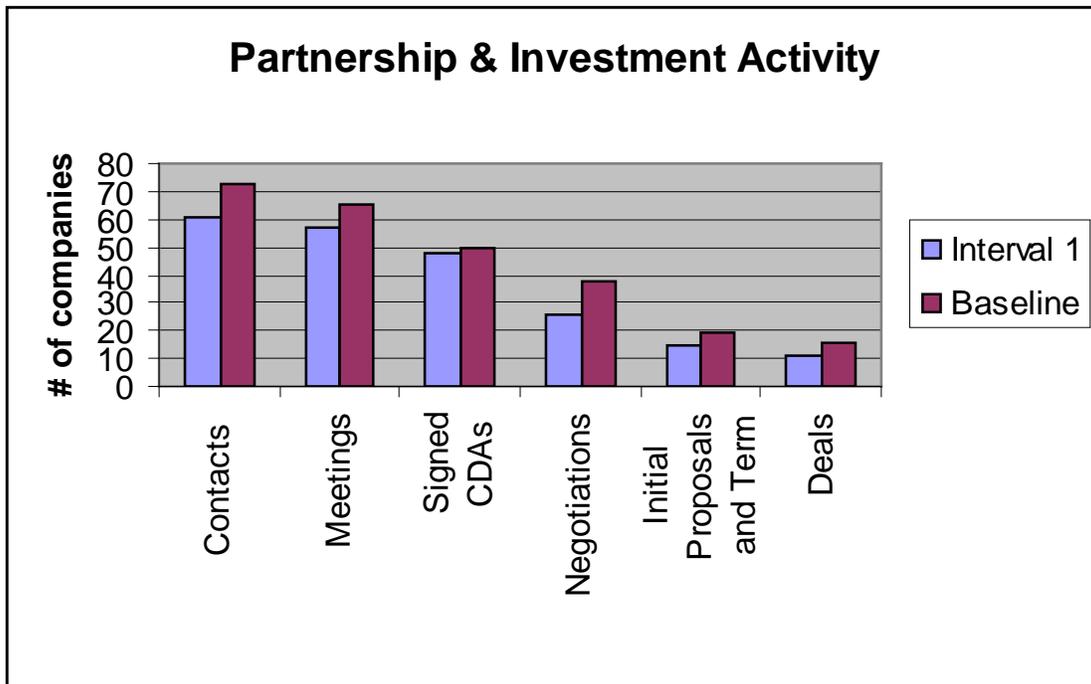


The chart below outlines commercialization progress with respect to partnership and financing deals, excluding the 31 companies that were non-responsive to the tracking request. Out of the 77 companies that responded to the first interval tracking request, an encouraging 67 companies or 87% of the companies indicate commercialization progress in the partnership and financing deals area.



“Progress” is defined as at least one event in at least one commercialization category shown in the table below:

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;

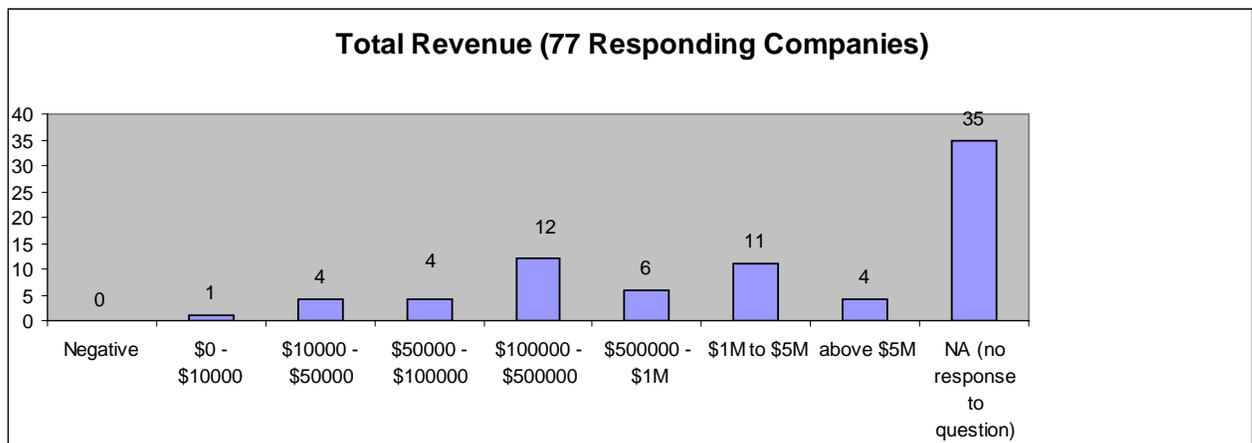
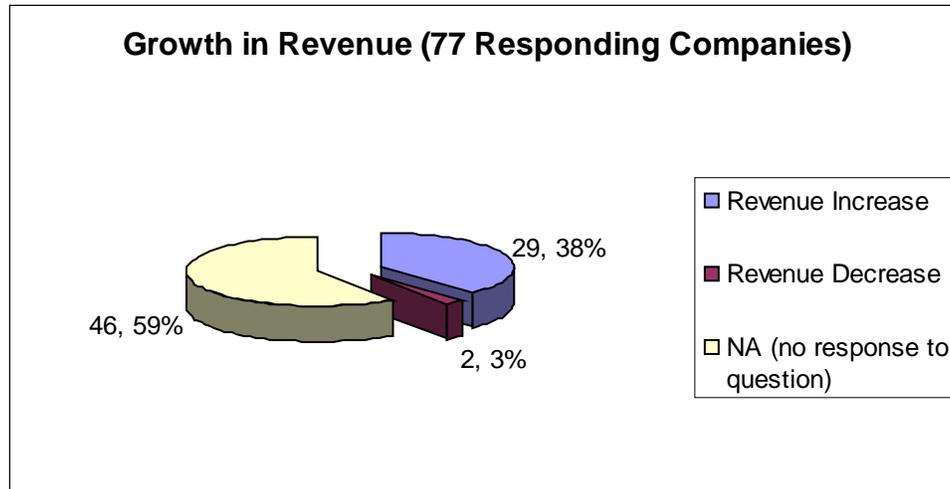


Key observations:

- The number of companies in all categories is lower for Interval 1 indicating lower number of respondents; however the overall pattern of activity is as strong as before and the intensity has increased considerably as follows:
- Contacts with investors and partners stood at 641 in the first interval compared to 544 in the baseline period, an 18% increase.
- Negotiations with investors and partners stood at 129 in the first interval compared to 77 in the baseline period, a 68% increase.
- 43 deals occurred in the first interval versus 23 in the baseline period, an 87% increase!

Growth in Commercial Revenue

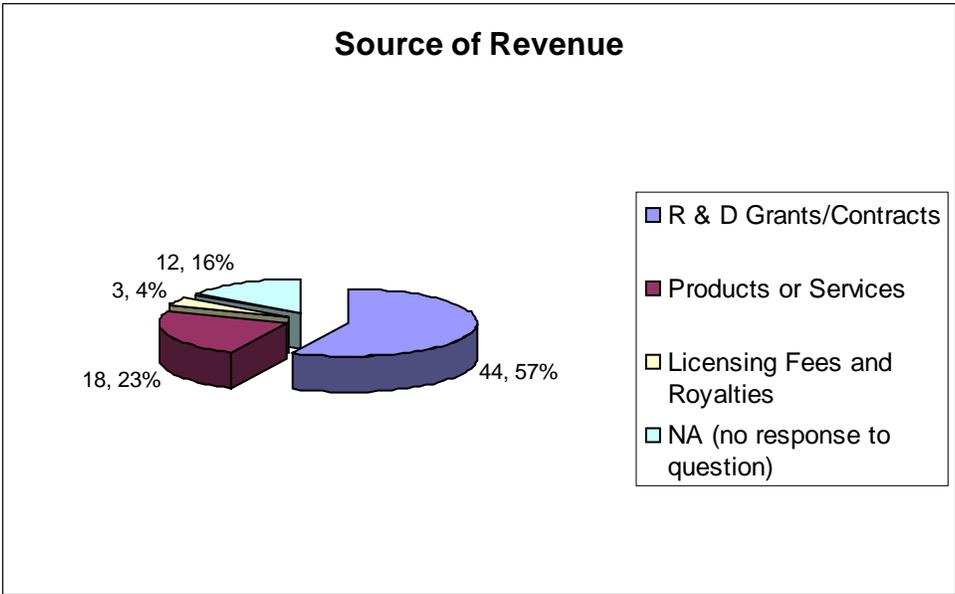
Note that the growth in revenue refers to the change in total company revenue rather than the revenue based on the CAP technology. This approach was taken in anticipation of the reluctance of companies to provide detailed revenue data.



Key observations:

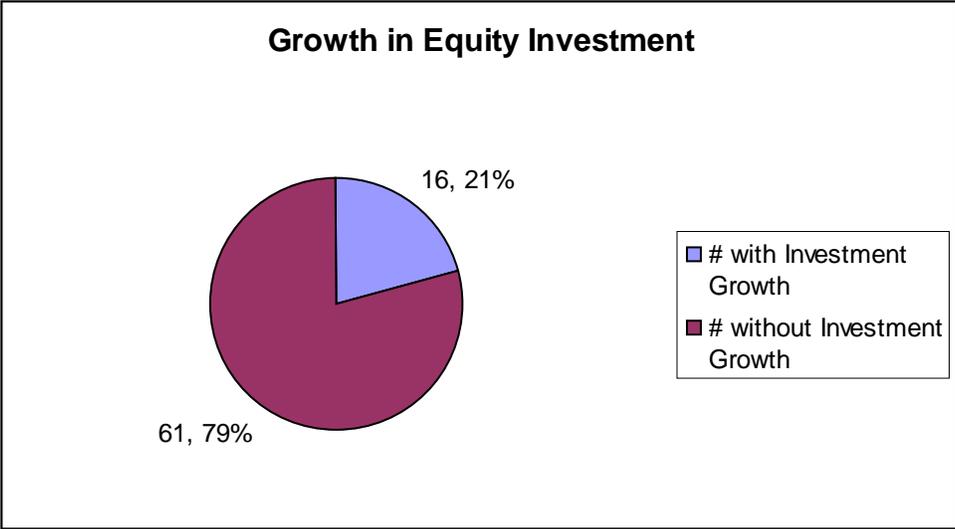
- 29 companies (38% of responding companies) have shown revenue growth.
- None of the responding companies have reported negative total revenue.
- The highest revenue growth reported was \$2 million.
- 4 companies have reported total revenue of over \$5 million and 11 companies between \$1million and \$5 million.

However, R&D Grants/Contracts remain the largest source of total revenue for 57% of companies, as shown below.

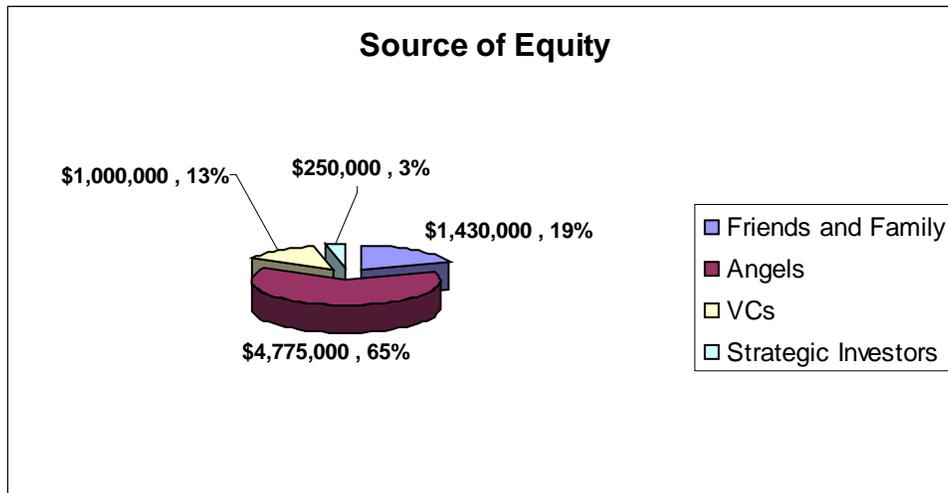


Growth in Equity Funding

The data, of course, refer to the growth of the equity funding for the company as a whole. 16 companies or 21% indicated an increase in equity funding and from one or more sources of equity funding; essentially the same percentage as in Baseline.



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



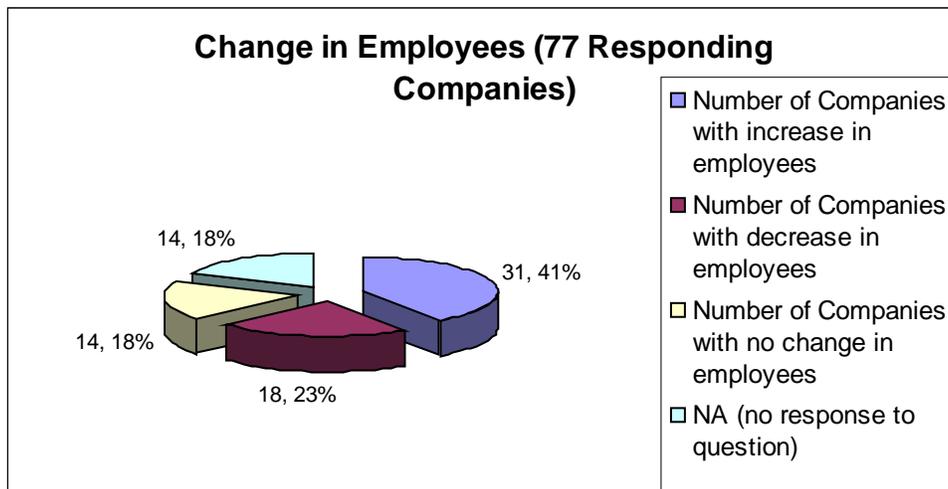
Key observations:

- Angel funding accounted for the largest source of equity funding.
- In total, \$7.5 million was raised by the 16 CAP companies that were successful with equity investment, down from \$15 million in the baseline period.
- The bulk of funding went to [REDACTED] (\$3 million in angel funding), [REDACTED] (\$650 K in VC funding) and [REDACTED] and [REDACTED] (both raising \$400 K each in angel funding).

Other Success Indicators

Employees

31 companies or 41% of the respondents indicated an increase in the number of employees with an aggregate change in employees standing at 138.



Mergers & Acquisitions

No mergers and acquisitions were reported in the first interval since the culmination of the 2004-05 CAP.

CAP Impact

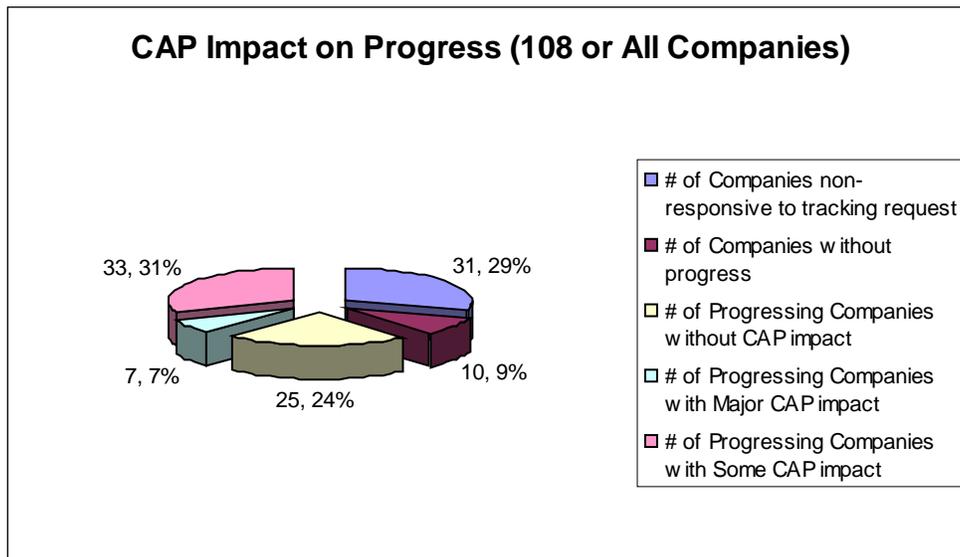
CAP Impact was rated by the companies as either 1) Major, 2) Valuable, 3) Minor or 4) No Impact. CAP impact was determined for the following activities that have been addressed earlier in the report.

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

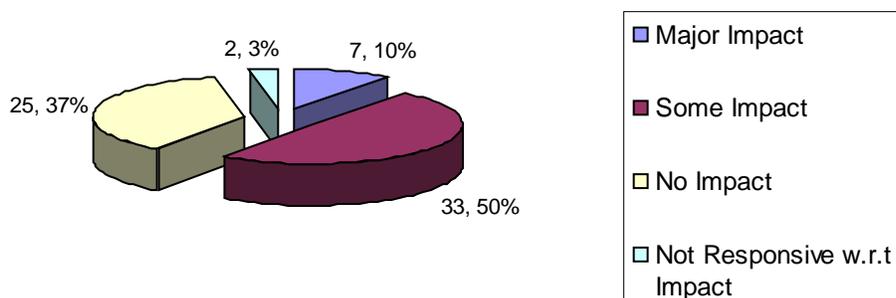
Note that the data here represent companies' subjective assessments on the impact of CAP on specific commercialization outcomes. Companies have separately outlined their feedback on the CAP, the results of which have been submitted to NIH.

Activity in Partnerships and Financing Deals

Progress is defined as at least 1 activity in at least 1 of the partnership and financing deal categories.



CAP Impact on Progress (67 or Progressing Companies)



Key observations:

- 7 companies have attributed the CAP with major impact and 33 companies have attributed the CAP with some impact.
- 62% of the progressing companies have attributed some or a major impact to the CAP on partnership and financing activities. This compares favorably with 40% in the Baseline.

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.

“One VC group very interested has picked up \$5000 of cost to do a market assessment. A meeting was held with [REDACTED] execs to explore partnership. This did not happen in the end. Preliminary contacts with [REDACTED] and [REDACTED] have been made.”

“Too early for one investor but a second investor is very interested and a fourth meeting will occur soon.”

“CAP shifted my thinking from scientist to CEO and all of the above got started.”

“Selected for [REDACTED] commercialization assistance grants and for [REDACTED] program that places companies in contact with Angel and VC investors. Potential partner concluded that [REDACTED] could not be ready for the clinic soon enough to meet their needs. Without the contacts I made at CAP, I would not have received support from [REDACTED] or from [REDACTED].”

We executed a term sheet with [REDACTED]. This is a firm that we met through the CAP program. Unfortunately, we never closed on funding with this firm. We are still using materials that were initially developed during the CAP program

“Several demos with each potential partner since January 2006. Discussions about mutual benefits for partnerships. Plans for additional meetings with [REDACTED] and [REDACTED] of the companies with which we have had discussions are a direct result of our CAP plan.”

“Multi-site training and networking meetings proved an excellent experience for the start-up companies like us.”

“The CAP program provided excellent insight into what may be expected from both investors and potential partners in discussions. This year has been a particularly busy one for opening up dialog with potential investors and partners – I expect this activity to increase as we get closer to product launch date.”

“Although no money deals were closed, I certainly am much more confident of the worth of our products and the worth of joint effort to develop a new product.”

“Major meeting with [REDACTED], smaller ongoing discussions with other potential partners

Most parties very interested in technology, want more clinical data to support. Several devices have been coated and sent back to partner for evaluation.”

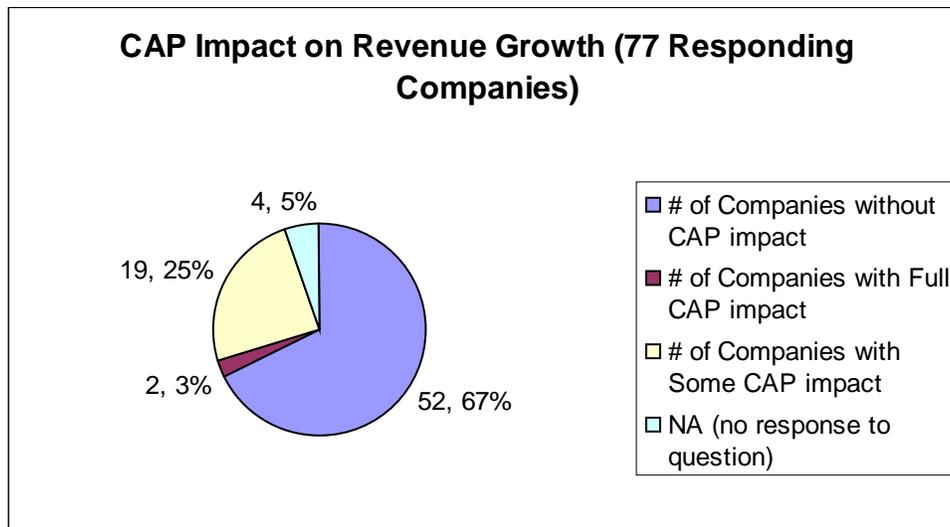
“Two of the contacts that led to serious discussions were a direct result of the NIH-CAP Venture Forum meeting.”

Some other companies that attributed the CAP with no impact had this to say:

“The NIH-CAP program was very useful in helping us to present the company to investors and/or joint venture partners. Unfortunately, no meetings or deal were consummated as a result of this program.”

“Although the CAP program per se did not impact our partnering activities, the SBIR grant and the data we generated with it was very important.”

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 the CAP impact on revenue.

Key observations:

- 21 companies or 28% of the companies that responded to the tracking effort have attributed the CAP with impact on revenue growth.
- [REDACTED] found the CAP to have a full impact on its revenue growth stating, “Company product sales first quarter 2006 equaled all sales in 2005 for biomedical

products. CAP played a major role in assisting the company in fine-tuning its marketing strategies.”

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

“It is now too early to estimate the impact of the CAP. We anticipate the effect in several months. Our company recently survived long funding gap. With new SBIR funds we hope to realize the potential given to us by the CAP.”

“CAP related product still not commercially available – planned launch at the end of 2006.”

“We are not yet producing revenue from our SBIR technology.”

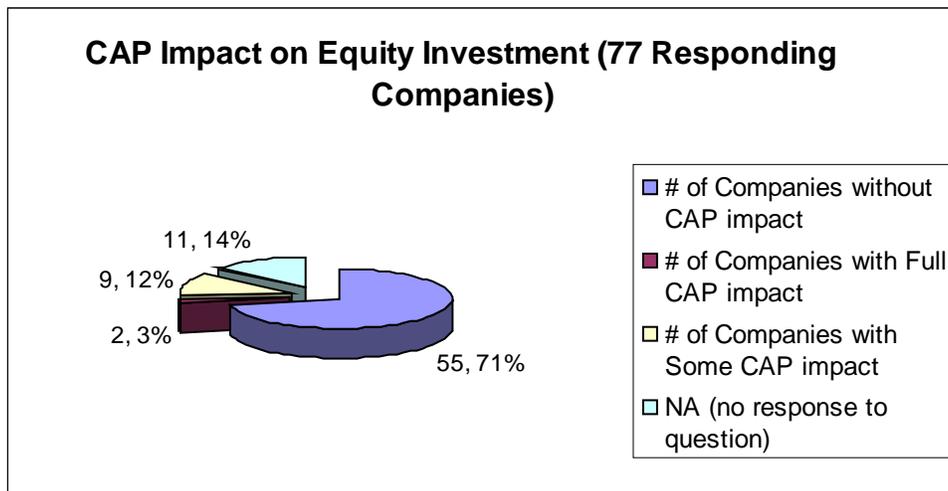
“Company is in formative stage – no products/services are for sale at this time.”

Other comments include:

“My participation in CAP has negatively impacted revenue from SBIR grants because I am spending less time writing grants and more time in commercialization activities. If the commercialization activities pay off, this will move the company into a new phase.”

“Program should offer an active session for exposing the new technology and products to potential customers and partners e.g. group meeting with US pharmaceuticals and distributors.”

Growth in Equity Funding



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

Key observations:

- 11 companies or 15% of the companies that responded to the tracking effort have attributed the CAP with impact on growth in equity investment. This compares with 18% in the Baseline period.

Comments from these companies include:

“The CAP program provided a valuable foundation from which we have proceeded, but did not directly impact the activity of this period. We have initiated discussions with [REDACTED] venture capital, with the help of our CAP advisor, but it is too early to tell.”

The comments from other companies indicate that several of them are not seeking equity funding or are working on other milestones before working on raising funding. The impact of CAP in these cases is therefore none. See below comments from companies in such cases:

“Not currently seeking investment, we are currently focused on product development and commercialization activities.”

“Company has not been actively looking for equity investment to date. Company is reasonably well funded and has been cash flow positive. The R&D investment in the CAP related product continues to increase & it is likely that as we near launch date that additional equity investment may be desired.”

“The company has an existing private investor base which has re-invested several times.”

“We have intentionally not sought external early stage investment.”

“[REDACTED] is traded in NASDAQ. No private investment was received during last and this year.”

“The company has decided to build further value by completing its product development activities and increasing revenues prior to seeking investment.”

Summary

The response to the first interval of progress tracking was encouraging with a response rate of 71%. The companies are actively pursuing various commercialization channels, with some experiencing success with equity financing and others making headway with strategic partnerships. Several companies are working out internal business issues, developing their product and exploring marketing prospects before looking for funding. The CAP has been successful in impacting company partnering and financing efforts especially, although the impact on revenue continues to be modest. Key results are summarized below:

	Baseline	Interval 1
Revenue Growth	NA	\$19.4 Million
CAP Impact	11%	28%
New Equity Investment	\$15 Million	\$7.5 Million
CAP Impact	3%	15%
Employment Growth	79	138

11 companies reporting a deal is encouraging as well as the revenue growth reported for this interval. The final progress tracking for the 2004-05 CAP companies will be conducted in January 2007 for the period April 1, 2006-December 31, 2006

APPENDIX A

2004-05 CAP companies relieved from tracking:

Company Name	Notes
[REDACTED]	Relieved of further tracking as company was involved in the program for a very short period.
[REDACTED]	[REDACTED] has now dissolved and closed out with the NIH.
[REDACTED]	Relieved from further tracking upon company's request and also it attributing no impact to the CAP.
[REDACTED]	Company feels that it is in very early stages of development and would like to be tracked once they make some headway with their technology and its commercial application.
[REDACTED]	The company has completed CAP requirements, but has requested to be relieved from further tracking.
[REDACTED]	[REDACTED], CAP leader has left the company and the company cannot commit to the remainder of the program.

APPENDIX B

NIH-CAP 2004/2005

COMMERCIALIZATION PROGRESS TRACKING FORM- INTERVAL TWO

July 1 2005-March 31 2006

PLEASE RETURN BY APRIL 21, 2006 TO KSOOD@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. This second interval of tracking will track your progress during the period of July 1, 2005 to March 31, 2006. We 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 July 1, 2005 and March 31, 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 July 1, 2005 and March 31, 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 July 1, 2005 and March 31, 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 July 1, 2005 to March 31, 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 July 1, 2005 and March 31, 2006.

_____ (\$millions)

b) Please state the *total revenue* as of March 31, 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

July 1, 2005 to March 31, 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 July 1, 2005 and March 31, 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

July 1, 2005 to March 31, 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 July 1 2005? If yes, please specify the number of employees in July 1, 2005, versus the current number of employees, and the titles/positions of the new employees.

	Employee Information
Number of Employees in July 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