



Best Practices for Grant Application

November 2018

Before we begin...

- Guidance based on my experiences
- Use this information at your own discretion
- HUGE THANKS to NJSBDC/Rutgers Business School

Personal background

Started at DNA Plant Technology as a manager of Analyte Group (1986), next joined ActiMed (1993) with a focus on chemistry processes and spent 17+ years at PortaScience(2000-2017), VP of R&D 10 years. At PortaScience we were very successful with grants and commercializing the technologies. Started IVDS full time in March 2017.

Chemistry

- 25+ years experience in product development and solid phase chemistry.
- Expertise lies in formulation chemistry, blood separation, and the semi- and quantitative determination of analytes in biological fluids.

Patents & Grants

- 4 US Patents PS
- Either PI/ Co-Author of 12 Successful SBIR grants

Commercial

- Instrumental in 10+ commercial products, key licensing agreements
Many from NIH
- All were Point-of-Care Diagnostic Tests

First FDA Approved Home Device for Measuring Cholesterol



IVDS overview, Started in 2017

In Vitro Diagnostic Solutions (IVDS)

Creating the next generation Point-of-Care (POC) tests for rare metabolic disorders by combining innovative chemistry and latest technologies.

We Offer:

- Contract development of dry and liquid phase chemistries (client work)
- Portable and affordable POC Devices
- Test Strip Design and Meter Integration
- Microfluidic Design
- Protein and Enzyme Stabilization
- Rapid Whole Blood Separation
- Novel Colorimetric Assay Development
- Control Solution Development and Stabilization

Mission: To build strategic relationships with industry partners to license, manufacture, and market POC tests for determination of Rare/Novel analytes.

IVDS plans for the future

Near-term

- Continue to develop our platform and portfolio for the diagnosis and monitoring of rare metabolic disorders
- Use commercially available test strip platform and reflectance based meter (Licensing Agreement)
- In parallel, continue to develop IVDS's own improved, hand-held meter

Long-term

- Implement a Quality Management System
- Set up Internal Manufacturing Process

1st
Generation



2nd
Generation



IVDS team

Deep scientific understanding and strong experience in bringing devices to market

Rob Harper

President & Founder



- 25+ yrs. in medical device diagnostics
- 10+ commercial products
- 5 U.S. Patent, 3 pending
- PS + IVDS 16 successful SBIR grants author/ co-author PI

Jordan Seville

Formulation Scientist



- Extensive Experience in Formulations
- New Product Development (G6PD, PKU, Bilirubin)
- Glucose POC
- Multiplexing & Microfluidics

Amy Chevalier, PhD

Research Scientist



- New Product Development
- G6PD Project
- PKU Project

Pranav Ponnaluri

Head of Business Development



- Commercial Strategy
- Fundraising & Partnerships
- Market Research & Analytics

IVDS' Scientists: pattern of success with previous companies

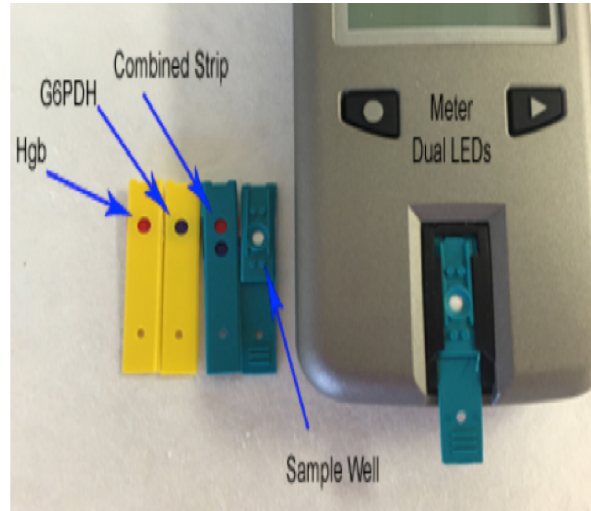
Our Group has helped bring 10+ products to market, many with the help of the NIH

Examples of FDA approved products

- POC Finger-stick Hemoglobin Test (Stan Bio Life Science) FDA approved
- POC Custom Red Cell Separation Membranes (Currently being used by Polymer Technology)
- POC Beta-hydroxybutyrate (BHB) Test (Stan Bio Life Science) FDA approved
- A POC Fertility Test (NIH Funded)
- POC Non-Instrumented Prothrombin Time Test (Technology Licensed) (NIH Funded)
- POC Lactate Dehydrogenase (LDH) Test; Milk Dairy Industry
- POC Leukocyte Count Test (NIH) / Somatic Cell Count; Milk Dairy Industry
- Gamma Hydroxybutyrate (GHB) Test; Urine (NIH Funded)



Stat Site Hgb



Glucose-6-Phosphate DH



Gamma-Hydroxy Butyrate
"Date Rape Drug" Detection

SBIR awards for IVDS

SBIR awards have made IVDS possible: 4 Grant approvals in 18 months for POC tests for diagnosing and monitoring rare metabolic disorders.

NIH Grants

- POC devices for the Quantitative Determination
 - Glucose-6-Phosphate Dehydrogenase (G6PD) Anti-Malaria 1:8,000
 - Phenylketonuria (PKU) 1:10,000
 - Conjugated and Unconjugated Bilirubin (Jaundice)

1st NSF Grant

- POC devices for the Quantitative Determination
 - Glucose-6-Phosphate Dehydrogenase (G6PD), Meter Development (non-overlapping Aims w/ NIH grants)

Grant writing: My key lessons learned

1. You need to have a great story. What is transformative about you technology
2. You need to have a great story with data
3. Define how and where your technology fits, which Division?
4. Find Champions
5. Give Yourself Time
6. Don't Lose Easier Points
7. Ask and Justify Max \$ in your Budget

Have a great story

Why is your technology Novel or Unique

- ~~Cost ?~~
- ~~Ease of Use?~~
- Ease of Use and Cost less? Maybe
- Changes Current Paradigm, Easier to Use and Cost Less A Great Story
- Why must the government give you money?

Have a great story with data

- Preliminary Studies (not required for Phase I ?...)
- Preliminary Data is Essential
 - Preliminary data provides evidence of the viability of proposal. Aims are your next Steps
- Review <https://grants.nih.gov/grants/funding/sbirgrantsmanship.pdf>
 - Great advice on writing your proposal!

Define how and where your technology fits

If unsolicited, what Division of the NIH does your technology fit in?

Contact your Program Officer via email

- If at all possible speak to them.
- Be well prepared.
- Do you believe this is a good fit for your division?

Find champions

Academia champion

+ Letter of Support (LOS)
Reviewer

Industry champion

+ Letter of Support (LOS)
Reviewer

- Follow up with an email and “Soft Letter of Support” (as a convenience) to edit
- Speak with them about your work.
- Strong Letter of Support “Well justified use of NIH Funding”
- The date of the letter should be 1-3 months prior to the submission date
- Reference “champions’ work (x)” in your application and cite their work in your Bibliography in **BOLD**

Give yourself time

- Start 3-4 months prior to due date.
- A good submission will require 300+ hours of writing.
- Have 2 peers review your Draft Application before submission.
- Have 2 peers review your Final Application before submission.
- Have GMS review your Draft and Final

Some points are yours to lose

- Detailed Facilities
- Detailed Biosketch
- Double-check and verify facts
- Align data in submission

Example: Stress facility details. Safety Oriented. Your Company has the infrastructure to make it work

General Laboratory.

In Vitro Diagnostic Solutions (IVDS) leases a 1,400 square foot laboratory facility. In addition to IVDS's technical staff, the company has an accounting service and marketing consultant. The facility has 4 computers, a conference room, projector, color printers; a label maker, scanner; and software for word processing, and utilizes Smart Sheets for project management. The laboratory is networked with high-speed internet access.

Clinical:

IVDS follows CLSI (Clinical and Laboratory Standards Institute; formerly NCCLS) guidelines described in M29 entitled *Protection of Laboratory Workers From Occupationally Acquired Infections* and GP5 entitled *Clinical Laboratory Waste Management*.

Stress Safety

The Biohazard bags are sealed and placed into a certified Biohazard Bin provided by the medical waste company, BioServ, for pick up.

The laboratory has lockable doors.

Proper use of Biohazard bags with vermiculite and proper sealing

Stress Safety

IVDS is registered with the Department of Environmental Protection pursuant to N.J.A.C. 7:26-3A.8 as a regulated medical waste generator in New Jersey.

Fabrication Dry Room.

This 120 sq. ft. is a dedicated area, humidity controlled, for the handling of enzyme and indicators and manufacturing of test strips. The Dry Room has the following manufacturing equipment:

Two Work Stations

Matrix Test Strip cutter 2501. (Kinematic)

Membrane Matrix Cutter 1201(Kinematic)

Desiccated Dry Box (SanPla Dry Keeper)

Foil Pouch Sealer (Global Industrial) provide capability of sealing aluminized pouches used to protect moisture sensitive or hygroscopic materials and product;

Analytical Balance (A and D Limited)

Color Printer Pictogram Maker (Kiaro)

R and D Laboratory.

Each Station is Equipped with a pipette station, spatulas, stir bars, kim wipes, test tubes and racks, Biohazard racks, biohazard bags and 70% IPA wipes

A Microscope Camera with Image-J analysis (Dino Lite)

A CO2 laser for prototyping (Full Spectrum)

Forced-air drying ovens (Yamato)

Drying Oven (VWR)

pH meters (Oakton)

Analytical Balances (A and D)

Ultrasound mixer (Vevor)

Refrigerator/Freezers (Haier/IDYLUS)

A -80°C freezer for storage of G6PD specimens

UV/Vis Spectrophotometers (Beckman)

Konica Minolta Chromameters — provide capability of measuring color full scan Percent Reflectance

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Focus on dollars and cents

Ask and justify maximum dollars in your budget

- “To the best of my knowledge an application is not rejected due to budget.”
- Request the \$225K and justify it properly
- Indirect: Negotiate the 40% Indirect Rate -- you will find you need it

Persevere Do not Get Frustrated

1. IVDS received scores above the pay line with our first 2 applications.
2. Summary Statements: Be Thoughtful and Thankful in your Introduction to your application. “We would like to thank the reviewers for their well-thought out, well justified input”.

Summary

- **Tell A Great Story With Data**
- **Have Champions LOS**
- **Start Writing Early**
- **Independence:** The **NIH SBIR** Grants have allowed us to start on a path of success!
- **Team effort:** Get Everyone Involved



And, again...

SPECIAL THANKS to NJSBDC / Rutgers Business School

and, specifically, Randy Harmon!



Thank you !