

# Revolutionary point-of-care, affordable early detection Lung cancer and Tuberculosis diagnostics

PITCH VIDEO INVESTOR PANEL



[pacediagnostics.com](http://pacediagnostics.com) Los Angeles CA

Technology Main Street Retail Medical Device Science

## LEAD INVESTOR



**Maria Rita D. Rosacia**

I have learnt that Pace Diagnostics and their team have worked for many years to develop their comprehensive portfolio of point-of-care rapid diagnostics that can provide quick result with simple steps, minimally invasive, and no expert/lab dependent. Since the tests are affordable and accessible, we can use them for mass population testing, therefore, more people can be tested and save lives. Pace Diagnostics are passionate about their science, their innovative products, their saving lives mission, and their investors. I am especially attracted to their positive social impact goal - save millions of lives, at the same time, I am impressed with the enormous financial opportunity for their investors - these are billions USD market sizes for TB and Lung Cancer diagnostics. It is great news for the investors who are enthusiastic about helping others and concurrently, receive positive financial upside.

**Invested \$20,000 this round & \$50,000 previously**

## Highlights

- 1 Raised \$2.5 million in seed investment; Won > \$6 million in grants from US DoD, NIH, and NSF
- 2 Huge markets and financial opportunities: 3.1 billion USD tuberculosis & 20 billion USD lung cancer diagnostics in 2022
- 3 Our products - low cost, accurate, non-invasive, non-lab dependent lung cancer & tuberculosis tests
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- 4 Our CE Mark is targeted by Q1 2022, allowing product distribution in EU countries; clear path to FDA clinical trials
- 5 We have a portfolio of proprietary material, filed patents and licensed IPs
- 6 Each year: 10 million new TB infections & 2 million deaths; 2.1 million new Lung Cancer cases & 2 million new deaths
- 7 Our TB test is specifically developed to meet all WHO requirements for performance, cost and use
- 8 British Biocell International (BBI) is our manufacturing partner



## Our Point-of-Care Diagnostics will help to save millions of lives – Positive Social Impact

- ✓ New cases of respiratory diseases like Lung Cancer are on the RISE. More lung cancer cases now are never-smokers and most are undetected until too late.
- ✓ We need simple, inexpensive, and accurate tests that will make screening and preventative healthcare choices convenient and affordable, for EVERYONE.

## Multi-Billion USD market for Tuberculosis and Lung Cancer Diagnostics – Financial Opportunity

- ✓ Our CE Mark is targeted by first quarter 2022, allowing product distribution in EU countries.
- ✓ Our target is to conclude FDA PMA Trials in 2022.
- ✓ We have proprietary materials, filed patents and licensed IPs.

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## Our Point of Care Diagnostics will help to save millions of lives

*our Simple Diagnostics for Better Living*

- ✓ Current clinical diagnostics for Tuberculosis (TB) and Lung Cancer are too expensive, too invasive, and too lab-dependent for large-scale population testing.
- ✓ Ten million people a year are infected with tuberculosis; ten to fifteen percent of one billion smokers get Lung Cancer. Non-smokers also get lung cancer. In part, due to the lack of affordable, easily accessible early testing, there are at least four million deaths globally because of Tuberculosis and Lung Cancer.
- ✓ With recent climate change, extreme weather events, and other social/industrial related factors (dust, smoke, chemicals etc), air pollution patterns are changing around the world, with a significant effect on respiratory health. These contribute to Tuberculosis and Lung Cancer new cases that are on the RISE, many are undetected until too late!
- ✓ A key to surviving lung cancer and other infectious disease like tuberculosis is catching it in its earliest stages, when it is most treatable.
- ✓ Pace Diagnostics has worked with the US Department of Defense, National Science Foundation, National Institutes of Health, and other leading global experts in tropical disease and oncology to develop and commercialize point-of-care tests for Tuberculosis and Lung Cancer.
- ✓ Pace Diagnostics is supported by a portfolio of proprietary materials, filed patents and licensed IPs.
- ✓ CE approval targeted by first quarter 2022 to allow products distribution in EU countries.
- ✓ Market Research Update: Huge Markets for Global POC Diagnostics \$81.4 billion by 2028; and Global Cancer Diagnostics \$280.6 billion by 2027.



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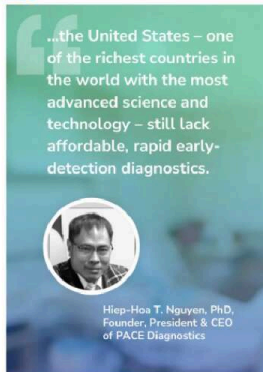
## How We Started

*GLOBAL DIAGNOSTICS FOR MOST URGENT DISEASES*

Originally from Vietnam, Dr. Nguyen experienced first-hand the consequences of inaccessible medical testing and treatment – testing or treatment unavailable, too expensive or not good enough.

As he helped and watched his parent fight their cancer battles, Dr. Nguyen realized that even the United States – one of the richest countries in the world with the most advanced science and technology – lack affordable, rapid early-detection diagnostics. His parent were diagnosed with stage III/IV cancer, despite their annual and regular medical check-ups.

To beat cancer and other diseases, Dr. Nguyen recognized the need for early detection tests that are affordable and accessible to everyone. He founded PACE Diagnostics to develop and bring these tests to everyone.



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## The Current Story - Unaffordable. Inconvenient. Ineffective.



*"The fight against TB is not just about how many people we treat, but how many we can screen."*

Dr. Seif Al-Albri, Dir. General, Directorate General for Disease Surveillance and Control, Oman

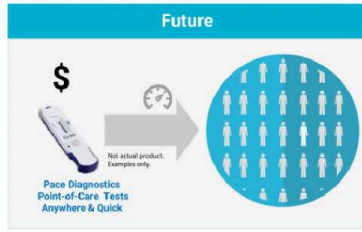
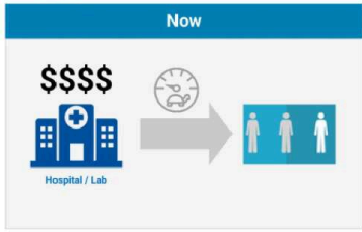
*"New evidence provides proof that there are real benefits to starting to screen (for lung cancer) at a younger age and among people with a lighter smoking history. We can not only save more lives, we can also help people stay healthy longer."*

Michael Barry, M.D., U.S. Preventive Services Taskforce

What we do



We are developing and manufacture accurate, affordable point of care tests that allow large populations to test where they are, with results in under 30 minutes.



The Overall Problem

Current tests for Tuberculosis (TB) and Lung Cancer have problems of cost, use, accuracy and the fact that provider needs lab, skills and time to process the tests.

Tuberculosis

Problem	Pace Diagnostics Solution
<p><b>*Current clinical diagnostics for TB are failing to detect a significant proportion of cases</b></p> <ul style="list-style-type: none"> <li>Inconvenient and time-consuming Requires returning to clinics. 2 days-&gt;2 week results turnaround</li> <li>Expensive and not available for mass application Molecular tests or IGRA tests</li> <li>Requires unique clinical expertise and instruments</li> <li>Invasive and difficult to obtain sample Like sputum samples from pediatric patients</li> </ul> <p><small>*Current global clinical diagnostics for Tuberculosis include Smear Microscopy, TB Culture, Chest Xray, QuantiFERON-TB Test, T-Spot TB Test and Gene Xpert MTB/RIF Test **Improved TB tests are still needed for sputum smear-negative, HIV-positive, pediatric populations, and for predicting reactivation risk of latent infection</small></p>	<p><b>PACE Diagnostics: A first-to-market, accurate, low cost, convenient POC TB diagnostic</b></p> <ul style="list-style-type: none"> <li>Easy-to-use, with results within 30 minutes</li> <li>Inexpensive and suitable for mass screening, new case findings and triage screening</li> <li>Minimal expertise needed for result interpretation With no need for additional instruments and consumables</li> <li>Minimally invasive, Point of Care application</li> <li>High sensitivity and specificity</li> <li>Capable of detecting TB in HIV-positive individuals where most current methodologies fail</li> </ul>

The Overall Problem

Current tests for Tuberculosis (TB) and Lung Cancer have problems of cost, use, accuracy and the fact that provider needs lab, skills and time to process the tests.

Lung Cancer

Problem	Pace Diagnostics Solution
<p><b>*Most of current clinical detection methodologies are failing to detect lung cancer early</b></p> <ul style="list-style-type: none"> <li>Typically too late in the progression of disease state</li> <li>Costly and inconvenient</li> <li>Not available for mass application or limited mass application due to complications (radiation exposure risk)</li> <li>Invasive and require clinical expertise</li> <li>High rate of false-positive results</li> </ul> <p><small>*The current Gold Standard for lung cancer diagnosis is Computed Tomography (CT)-Needle Biopsy method. CT Scans can be used to detect lung cancer and currently recommended annually by the USPSTF for high risk individuals</small></p>	<p><b>PACE Diagnostics: A novel, low cost, accurate, early detection lung cancer POC diagnostic</b></p> <ul style="list-style-type: none"> <li>Improved sensitivity &amp; specificity for early detection</li> <li>Highly affordable</li> <li>Suitable for mass screening, new case findings and triage screening</li> <li>Minimally invasive, Point of Care application</li> <li>Minimally invasive POC application, with minimal expertise needed for test result interpretation Results within 30 minutes</li> </ul>

Current Diagnostics Test vs. Pace Diagnostics Test

Problems with Current Diagnostics Tests			Pace Diagnostics Rapid Tests
<p>Expert-dependent to conduct and to interpret the scan</p> <p>Lab-dependent for specialized equipment &amp; procedure(s) (MRI, CT, PET, X-ray etc)</p> <p>High false-negative/false-positive rate</p>	<p>Extremely Invasive</p> <p>Expert-dependent to conduct and to interpret the scan and results</p> <p>Lab-dependent for specialized equipment &amp; procedure(s)</p>	<p>Minimally Invasive</p> <p>Lab-dependent for equipments and to perform the tests</p> <p>Time Consuming</p>	<ul style="list-style-type: none"> <li>Few Simple Steps - similar to at-home pregnancy test</li> <li>Minimally Invasive or Non-Invasive</li> <li>Affordable</li> <li>Accurate</li> <li>Quick Instant Result</li> <li>Accessible &amp;</li> <li>No-Expert Dependent</li> <li>No-Lab-Dependent</li> </ul>



## Problems with Current Diagnostics Tests

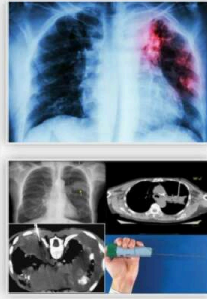
The World Health Organization (WHO) has set forth requirements - cost, speed, accuracy, and functionality minimums for a TB triage point of care test. **Presently, no test meets all requirements.** A few current tests meet some requirements but not all, especially the cost. Therefore, foundations and governments pay a portion or all of the tests' cost. However, that money is not always available, and even with the subsidy, prices are still too high.

Finally, even if their costs are minimized, these tests are not point-of-care tests that a non-professional can perform in a non-lab environment. This limits the tests that can reach people where they are, which ends up costing lot of lives.

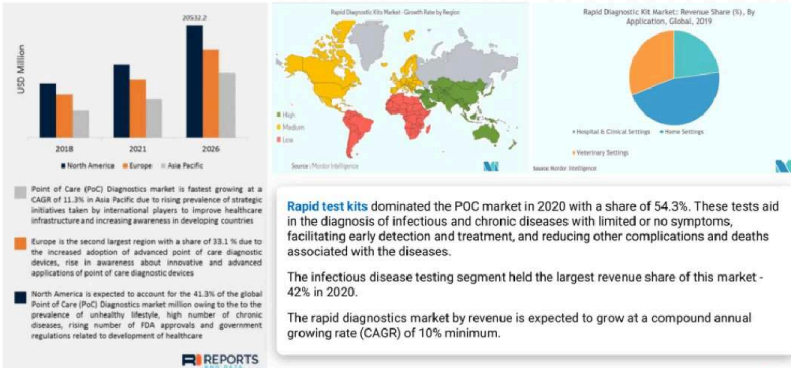
The current Gold Standard for lung cancer screening and diagnosis is Computed Tomography (CT)-Needle Biopsy method. CT Scans used to detect lung cancer and are recommended annually by the USPSTF for high-risk individuals. **Point-of-Care tests are not available for lung cancer screening today.**

The global health issues for lung cancer diagnostics are cost, equipment availability, and time. **Like TB screening, expensive equipment is needed, a professional is necessary to perform the screening, and expert analysis is required.** As a result, millions of cases are not detected early enough, costing lives.

Similar to TB, a confirmatory method is used for screening. Screening of mass populations cannot be done, but it could be with the Pace Diagnostics rapid screening test.



## Rapid Test Market to reach USD \$48.54 Billions by 2026



## Our lead products present a significant market opportunity

<p><b>\$81.4 billion by 2028</b> 9.4% CAGR from 2011-2028</p> <p><b>Global POC Diagnostics Market</b></p>	<p><b>\$280.6 billion by 2024</b> 6.9% CAGR from 2021-2028</p> <p><b>Global Cancer Diagnostics Market</b></p>
<p><b>\$3.1 billion by 2024</b> 4.1% CAGR</p> <p><b>Point of Care TB Diagnostics: Serviceable available market</b></p>	<p><b>\$4.3 billion by 2027</b> 8.1% CAGR 2020-2027</p> <p><b>Lung Cancer Diagnostics: Serviceable available market</b></p>

The WHO/FIND estimates the need of **>80 million TB triage tests** and **>50 million TB screening tests PER YEAR by 2022**  
(Source: Foundation for Innovative New Diagnostics)

Sources: <https://reports.valuates.com/market-reports/DYRE-Auto-202078/global-point-of-care-infectious-testing-market>, Grandview Research sept 2016 Global Cancer and Lung Cancer Diagnostics Industry Report May 2021 by reportlinker



## Company/Product Timeline to Market



2018  
 • Initial research  
 -> \$6 million government grants

2018  
 • British Biocell International (BBI) commences manufacture development process  
 • Patents filled for China, Mexico, India, Europe, Brazil

2020-2022  
 • Ospedale San Raffaele University (Partner of WHO) Co-Study  
 • Foundation for New Innovative Diagnostics Co-Study  
 • Peer Reviewed Papers  
 • Pre-Clinical and Clinical Trials  
 Projection Start (TB and Lung Cancer)

2022

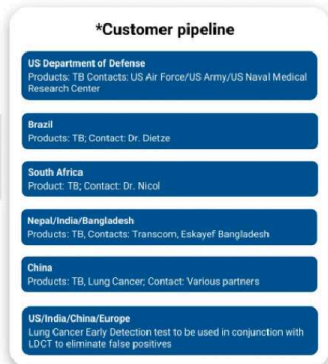


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## Our business model



\*Customer Profile - Our end customers include hospitals, doctors, NGO's, relief agencies, medical groups, health organizations.



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GLOBAL DIAGNOSTICS FOR MOST URGENT DISEASES

## Patents & Partners

PACE Diagnostics has a patent pending for our Novel Lung Cancer Diagnostic Markers and Combinations in the US. We also have patents pending for our Novel TB Diagnostic Markers and Combinations in the following countries:



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## Our partnerships include:

 <b>STOP TB Partnership</b> STOP TB Partnership, chartered by the UN	 <b>FIND</b> Diagnosis for all Foundation for Innovative New Diagnostics	 <b>BBI Solutions</b> British BioCell International Solutions
 <b>UFES</b> Federal University of Espirito Santo in Vitoria, Brazil	 <b>NATIONAL HEALTH LABORATORY SERVICE</b> National Health Laboratory Service (NHLS) of South Africa	 <b>UNIVERSITY OF CAPE TOWN</b> University of Cape Town
 <b>I.R.C.C.S. Ospedale San Raffaele</b> Gruppo San Donato IRCCS Ospedale San Raffaele - WHO Collaborating Centre and TB Supranational Reference Laboratory		 <b>UC San Diego Health</b> UC San Diego Health's Lung Cancer Screening Program



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**Do You HATE that You MISSED INVESTING in big companies at their EARLY STAGES? We have the potential, and you have the opportunity!**

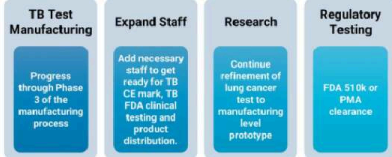
**\$200**

Become an investor in Pace Diagnostics, as little as \$200 – positive social impact with strong potential for financial upside

**Invest now to make Early, Easy, Accessible detection of Tuberculosis and Lung Cancer possible.**

With your investment, we will further manufacture Pace Diagnostics' Tuberculosis triage test and finalize research on the Lung Cancer early detection test. We also apply for CE mark to enable Pace Diagnostics to achieve revenue in 1.2 years; conduct FDA clinical studies, and complete US final regulatory clearance within two years.

**What's Next?**



**Recap: Summary of Pace Diagnostics' recent achievements**

CE approval targeted by first quarter 2022 to allow products distribution in EU countries	Supported by a portfolio of proprietary material, filed patents and licensed IPs
Clear path to FDA clinical trials	Our exit comparative company was bought by Qiagen for \$350 million
British Biocell International was selected as our manufacturing partner in 2019	The first tuberculosis triage test developed specifically to meet all stringent WHO requirements for performance, cost and use
Pace Diagnostics is progressing through the second stage of the manufacturing process	The first lung cancer early detection test that is inexpensive, can be used anywhere and meets top performance requirements
Attracted \$2.5 million in seed investment	Initial discussions with WHO/FIND for their endorsement for worldwide use



**JOIN US NOW and be PART of OUR TEAM**

Together we can make our world healthier, happier, better, and simpler. We can significantly improve our life with simple yet affordable preventive healthcare choices; and help to reduce the burden on our healthcare system.

The important key to beat any diseases especially cancer is catching them in their earliest stages, when they are most treatable. Our low-cost, easy-to-use, rapid diagnostic tests are an "overdue" solution for early detection needs.

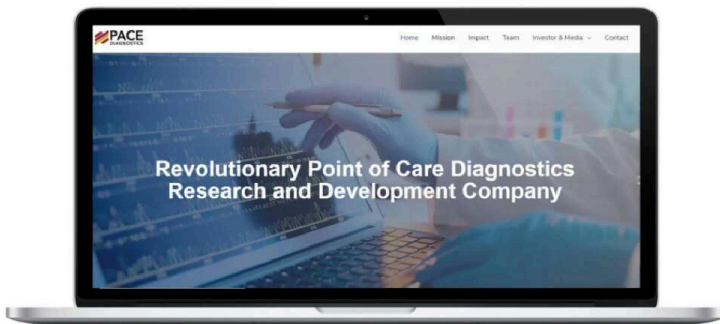
An investment in Pace Diagnostics is a "health" investment for a healthier life and a better world.

**INVEST IN PACE DIAGNOSTICS for ...**

- Social Impact:** Save Millions of Lives
- Financial Opportunity:** Huge Markets for Tuberculosis and Lung Cancer Diagnostics
- Earn Perks when you Invest**
- Innovative Products:** Point-of-Care Tuberculosis and early detection lung cancer tests



**Our Website**



[www.pacediagnostics.com](http://www.pacediagnostics.com)



**The Leadership Team**





Hiep-Hoa T. Nguyen, PhD  
President, CEO and Founder



Lorne Mattner, MBA  
COO and Co-Founder



Marianne MT Nguyen-Ballache  
CBO and Co-Founder



Sanjay Jayachandran, PhD  
Co-Founder



Victoria Nguyen  
Lab Director and Co-Founder

## Our scientific advisors



Prof. Davide Manissero  
MD



David Kane  
PhD, Consultant



Prof. Mark Nicol  
PhD, MD



Prof. Reynaldo Dietze  
PhD, MD



Prof. Sunney I. Chan  
PhD, Co-Founder



Prof. Lyudmila Bazhenova  
MD

[www.pacediagnostics.com](http://www.pacediagnostics.com)



# Appendix

## Team Qualifications

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### The Leadership Team - Qualifications

#### Hiep-Hoa T. Nguyen, PhD, Founder, President & CEO, Board Member

Dr. Nguyen has acted as President and Chief Science Officer for a number of biotech companies that he founded or co-founded. Dr. Nguyen received his Bachelor of Science in Chemistry and Bachelor of Science in Chemical Engineering, both summa cum laude from the Georgia Institute of Technology. He received his PhD. in Chemistry/Biophysics from the California Institute of Technology (Caltech). He was a recipient of a National Institutes of Health Pre-doctoral Fellowship and a WR Grace Fellowship while at Caltech pursuing his PhD. He was an American Cancer Society Postdoctoral Fellow while at MIT.

#### Lorne Mattner, MBA, Co-Founder, COO, Board Member

Mr. Mattner is an executive with a track record that includes building start up companies, both domestically and in Asia, fund raising and two successful exits. He earned his MBA and BS from the University of Southern California.

#### Marianne M.T. Nguyen, Co-Founder, CBO, Board Member

Mrs. Nguyen received her undergraduate and graduate training (technical and business) at Georgia Institute of Technology, UCI and UMass Amherst. She held various senior leadership positions with Honeywell Safety Products, Ametek Aerospace, Tyco International, ICI and various private ventures. She has over 25 years of leadership and industrial experiences in the areas of new product development, operations, supplier chain, business and program management. She also co-founded numerous startups and ventures.

#### Sanjay Jayachandran, PhD, Co-Founder

Dr. Jayachandran received his PhD from UC Riverside and was a National Institutes of Health Postdoctoral Fellow at University of Southern California.

#### Victoria Nguyen, Co-Founder, Lab Director

Ms. Nguyen graduated top of her class at Georgia Institute of Technology. After graduating from Georgia Institute of Technology, she went on to work for Western Digital, Motorola, Sony, IBM, AMD and FS international. She also co-founded various startups.



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### Board of Scientific Advisors – Qualifications

#### Prof. Davide Manissero, MD

Dr. Davide Manissero is currently the Chief Medical Officer of Infectious Disease for Qiagen and a Senior Lecturer at the University College of London. In the past, he held other positions at Qiagen, WHO, ECDC among others. He has published over 70 peer-reviewed articles and conference abstracts on tuberculosis and he is regarded as an expert in the field. He is also an associate fellow at the WHO Collaborating Centre for TB, Trondheim, Italy. He received his MD from Universita Cattolica del Sacro Cuore; MS in Tropical Medicine and International Health from London School of Hygiene & Tropical Medicine, University of London; and Diploma in Paediatric Infectious Diseases, University of Oxford.

#### David Kane, PhD, Consultant

Dr. Kane received his MA in Chemistry from the University of Cambridge and his PhD. in Biophysics from the Max Planck Institute (Frankfurt, Germany), and performed his postdoctoral study at the University of Southern California. Subsequently, he was a Global Business Director for Ogilvy, being responsible for all businesses with Boehringer Ingelheim (now Roche Diagnostics) worldwide. He also was a Managing Director and European Managing Director for Chandler Chicco Companies/Inventive Health. Currently, he is a Managing Partner for Arc Bio Communications, an independent Healthcare and Biotech Consulting firm.

#### Prof. Mark Nicol, MD, PhD

Prof. Mark Nicol is currently is Head of the Division of Medical Microbiology at the University of Cape Town and holds a joint appointment with the National Health Laboratory Service (NHLS) of South Africa. Prof. Mark Nicol received his MD at the University of Witwatersrand and his PhD in microbiology pathology at the University of Cape Town. He leads a research team focusing on the evaluation and implementation of novel diagnostic tests for tuberculosis and other respiratory tract infections.



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### Board of Scientific Advisors – Qualifications

**Prof. Lyudmila Bazhenova, MD**

Prof. Lyudmila Bazhenova is currently a Clinical Professor at UC San Diego, and Lung Cancer Unit Leader at Scripps Green Hospital. She is a board certified medical oncologist and hematologist with expertise in lung cancer. She received her MD at Nizhny Novgorod Medical Academy, Russia and completed her internal medicine residency at UCLA/WLA VA Medical Center, Los Angeles, CA.

**Prof. Reynaldo Dietze, MD, PhD**

Dr. Reynaldo Dietze is currently an Associate Professor of Medicine and Director of the Center for Infectious Diseases at the Federal University of Espírito Santo (UFES), Vitória, Brazil. Dr. Dietze was a former President of the Brazilian Society of Tropical Medicine. He is also a Clinical Trial Coordinator of the Brazilian Tuberculosis Research Network, Member of the Tuberculosis Committee at the TB National Program/Ministry of Health and Consulting Associate Professor of Medicine, Duke University Medical Center, Durham, NC, USA. Since 1990 Dr. Dietze has led a multidisciplinary team of investigators studying epidemiology, microbiology, molecular biology and immunology of infectious diseases, in particular tuberculosis.

**Prof. Sunney I. Chan (Emeritus – Caltech), Co-Founder**

Prof. Chan is the George Grant Hoag Professor of Biophysics, Emeritus at Caltech, and was Vice President (Emeritus) of Academia Sinica (Taiwan).

