Robert Imani, MD, PhD

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CURRICULUM VITAE

Highlight & Summary

CAR-T Cell
CRISPR
BiTE: CD19 & CD3
Small Molecules

MRD, Biomarker, ctDNA (CLIA)

Breast / Ovarian Cancer
NSCLC, CRPC, HCC
Pancreatic, Prostate Ca
GBM, SCCHN
Hematology & IO
Multiple Myeloma
Leukemia and Lymphoma
AML – MDS - RRMM
Endocrine & Metabolism
Women & Men's Health

Drug development expert and a seasoned veteran of the healthcare space who consistently obtains successful outcomes for midsized and boutique biotechnology and large pharmaceutical companies.

Highly adept at managing incoming safety information, risk assessment and mitigation strategies. Expertise in responding to ad-hoc domestic and global regulatory authority inquiries. Accumulated a series of successes in big pharmaceutical companies both domestically and globally.

Designed clinical development programs from clinical study design, inclusion exclusion criteria of the study population that required to be enrolled in the study according to the advisory boards, publication of class compounds, the interaction with the agency, as well as key opinion leaders in that indication.

Calculated sample size and performed preliminary power analysis to determine the optimal sample size that will ensure an adequate power to detect statistical significance that will reject the null hypothesis with high probability based on the sample estimates. Composed clinical study synopsis, and study protocol, ICF, and other core documents.

Initiated studies (IM presentations), Trained study site staff, Monitored eligibility, Medical Monitoring, etc.

Reviewed the final draft TFLs according to SAP, presented the data to the upper management teams.

Completed numerous early, mid as well as late-stage clinical trials in Oncology. Led study initiation and completion within the allocated budget and timelines. Ensured data haven been captured, analyzed, interpreted, and presented to the executive management team as well as external stakeholders (press releases, international societies, regulators, as well as investor community). Demonstrated favorable safety efficacy profile of investigational compounds.

Focused on technologies such as "CAR-T Cell, BiTE (CD3-CD19) and antibody drug conjugates (ADP), small molecules, and antigen presenting cancer vaccines for targeted therapy while using circulating tumor DNA (ctDNA) we have been trying to detect individual response (PFS/OS) using ultrasensitive detection of molecular residual disease (MRD) in Myeloma, Lymphoma and other hematologic as well as solid tumors (e.g. HPV-18, HPV-16 related squamous cell carcinoma of head and neck (SCCHN) or gynecological malignancies.

Special interest in malignant disorders such as Multiple Myeloma, AML, MDS, HL, NHL, Ovarian & Breast cancer, NSCLC, HCC, GBM, SCCHN, Thyroid, Pancreatic and Prostate Cancer. Please refer to the details of Phase 1/ Phase 2/ Phase 3 clinical trials listed below.

Worked closely with operation, quality control, regulatory affairs departments Prepared for type C meetings to agree with the FDA on the path forward. Worked closely with key opinion leaders to publish the study data from efficacy and safety point of view in peer reviewed journals with high impact factor. Discussed clinical relevance of efficacy/safety data in multiple forums.

Composed clinical study protocol, ICF, IB, ICSR, DSUR, and CSRs after completion of the studies. Reviewed TEAEs, SAEs. Reviewed ICSR of SUSARs and reported according to regulations, SOPs, and industry standards.

Designed clinical development programs, activated, enrolled, ensured review of eligibility of each subject prior to enrolment in the study. Assumed medical monitoring tasks. Responded to inquiries from the clinical study sites. Led investigator meetings with sponsor and CRO.

Ensured data cleaning, data capture, data lock (data read) on a timely fashion. Reviewed TFLs. Analyzed data according to SAP. Presented to executive Management. Ensured timely press releases would go out working closely with public relations team. Submitted abstracts to the international societies. Presented at conferences together with the investigators. Led Advisory boards.

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Granted Pharmaceutical Marketing Authorization From IND to NDA

More than 2 decades of Professional Experience in Pre-clinical, Clinical, Medical Affairs, Drug Safety and Post-Marketing Research of Investigational Medical Compounds, Product Launch, and LCM of Approved products.

- 15+ years of supporting, managing and/or leading clinical research or drug development industry from sponsor's side (small/mid biotechnology and large pharmaceutical corporations) and acidemia clinical research management sites clinical study sites from Phases I through IV, and 10+ years of contribution to and accomplishment in all aspects of conducting clinical trials (e.g., planning and executing clinical trials, data cleaning, data lock and TFL review, ICSR review, cumulative (integrated efficacy summary; IES) reports as well as cumulative (integrated safety summary; ISS) reports which needed to be submitted to health authorities (EU/US regulatory agencies) in a global/matrix environment in the pharmaceutical industry.
- Focused on technologies such as "CAR-T Cell, BiTE (CD3-CD19) and antibody drug conjugates (ADP), small molecules
- Excellent conflict resolution expert. I have advanced knowledge of specific therapeutic area (TA listed on page one of my CV). Established strong scientific partnership with PIs, Co-PIs, KoLs, sponsors, and other key stakeholders. I. have thorough knowledge of drug development excellence, biostatistical analysis methodology, ICH guidelines, GCP, clinical study setup per endorsed clinical development plans that put together, clinical study design (ICF, CRF, study synopsis & full study protocol) and amendments of core documents (ICF, clinical study protocols, CSR, RMPs, per SOPs.
- 7+ years people management experience in a matrix environment. Excellent communication skills, written and oral. I have demonstrated ability for being a good listener as well as an expert in negotiating with various stakeholder for conflict resolution due to the interpersonal skills and experience that I have accumulated in time.

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Professional Industry Experience

AITERO – San Diego, CA 2017 – Present

Executive Medical Director

Clinical Research & Development

Hematology, Oncology, IO, Endocrine, CNS, Rare diseases

Sponsors/Clients: BioMarin, BMS, AMGEN, AbbVie, Ultragenyx, Celgene, Takeda, Genentech, Ziopharm, Xencor, Sumitomo Dainippon Pharma, Cell Design Labs, Sangamo and SanBio.

Technology: Small and large molecules, Biologics, Biosimilars, Antibody drug conjugate (ADC), CRISPR, and CAR T-Cell technology

I focused on technologies such as "CAR-T Cell, BiTE (CD3-CD19) and antibody drug conjugates (ADP), small molecules and led clinical development program of all clients of AITERO Consulting Group from Clinical/Medical/Scientific, MA, and PV Perspective. As a core member of clinical development team (CDT) and product safety team (PST), monitored patients enrolled during Phase I a/b and 2 a/b, and Phase 3 clinical trials for assigned products. Led clinical development program, Medical and Scientific as well as relevant safety operation and risk management issues as summarized below.

I also led clinical development strategy. Composed Clinical Study Protocol. Ensured consistency of scientific and development strategies for clinical development programs Provided clinical leadership, strategic as well as daily tactical medical and scientific input for all assigned projects. Presented at Investigator meetings, reviewed eligibility, enrolled subjects, ensured enrollment in the study continues as planned, cleaned/locked the study data, reviewed top line data captured in TFLs per SAP. Composed study synopsis (outline), biostatistical section, study design, and Clinical development plan that got endorsed by upper management. Led the clinical development program of all clients of AITERO from a medical and scientific perspective. I was responsible for composing study synopsis, clinical development plan, and clinical study protocol that were endorsed by upper management, as well as presenting at Investigator meetings, reviewing eligibility, enrolling subjects, and ensuring enrollment in the study continued as planned. I supervised a team of MDs, PhDs, and RNs, managed individuals reporting to my position, and ensured consistency of scientific and development strategies for clinical development programs. Additionally, I provided clinical leadership, strategic as well as daily tactical medical and scientific input for all assigned projects, monitored patients enrolled during clinical trials, and oversaw the PVRM activities of assigned investigational medicinal products. I also prepared, edited, and finalized core documents, including the study synopsis of clinical study protocols, investigator brochures, synopses, regulatory documents, and related clinical documents such as abstracts, posters, presentations, and manuscripts. Furthermore, I led the strategic planning, oversight, and management of the assigned clinical program(s) from an end-to-end clinical development perspective, led the preparation of the global Clinical Development Plan (CDP) and Clinical Trial Protocols for assigned product candidates, and organized and led scientific review boards (SRBs) for assigned products. I supervised and directed my direct reports, communicated with internal and external stakeholders, interacted with health authorities on assigned projects, monitored and reviewed medical data for clinical trials that were completed, analyzed, presented, and interpreted the data from clinical studies, led medical communications and publication task force with focus on executive management of all facets of clinical development at the time of NDA filing, and collaborated with cross-function teams, including RA, PVRM, clinical operations, data management, statistical analysis, QC, CMC, and other departments. I reviewed CRFs, draft and final datasets and TFLs, database specifications, eCRF completion guidelines, medical coding conventions, data management QC plans, data validation plans. I also composed and finalized CSRs and reviewed training slide decks for clinical sites for the next phase clinic study site's startup. Finally, I performed medical review of incoming information for assigned pre-and post-marketing products (PVRM), assisted with the execution of clinical studies to establish the safety, efficacy, and commercial viability of new products, and actively participated in site selection and assisted with providing oversight to assure investigator compliance with the study protocols, regulatory guidelines, and company standard operating procedures.

Sumitomo Dainippon Pharma – VP 2017 – 2017

Assumed Roles and Responsibilities of an Interim VP till a local candidate was hired.

Clinical Development, Hematology, Oncology, IO

Technology: Small and large molecules

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Please refer to previous page as SDP was another client of AITERO with an interim VP title.

Onyx Pharmaceuticals (AMGEN) – San Francisco, CA 2012 - 2016

Executive Medical Director

Clinical Research & Development. (3 BTD programs), Hematology, Oncology, IO

BTD Programs, conditional accelerated approval based on positive Phase 2 data,

This led to a Dual Role in Medical Scientific Affairs as well as Clinical Research and Development

CAR-T Cell technology at Kite (ABP of AMGEN): I focused on technologies such as "CAR-T Cell, BiTE (CD3-CD19) and antibody drug conjugates (ADP), small molecules and led clinical development program of all clients. **BiTE Technology: 2 BTD approval using 1 Phase2 study submission:** During my tenure at ONYX Pharmaceuticals (an AMGEN subsidiary), as a core member of the clinical development team (CTD) lead at ONYX Pharmaceuticals (an AMGEN subsidiary), I led the development of Investigator Brochures for safety sections, including Reference Safety Information, and implemented processes for signal detection and management. I kept up to date with industry practices and regulatory changes to ensure effective benefit-risk evaluations prior to marketing authorization or during post-marketing activities, such as accelerated conditional approvals. I provided technical oversight to project teams and contributed to project deliverables in the areas of PVRM and collaborated with cross-functional teams during label negotiations and prior to marketing authorization. I also conducted medical review, ensured the accuracy of safety information, and led medical communications and publication task force.

Additionally, I contributed to the implementation of strategies to ensure patient safety and mitigate potential risks and participated in cross-functional safety review committees. Overall, I completed documents according to agreed-upon timelines and followed up with study teams, while initiating new committees, leading key initiatives and publications, and monitoring the safety profile of IMPs and approved products in phase II and III studies.

ODAC: Additionally, managed and led ODAC with a positive voting that led the FDA provide conditional approval with post marketing commitments (3 pivotal. Registrational studies be conducted and submitted 5-6 years later for full approval. Conditions were lifted (Pos. P3 data).

GMA (PLP, LCM): Maintaining professional knowledge and accreditation is a top priority for me, and I actively participate in CME activities. I have contributed to the implementation of strategies to ensure patient safety and mitigate potential risks and have developed, updated, and composed clinical study reports to internal teams on safety issues. Additionally, I have contributed to updating core safety information inserted in core documents and have conducted medical reviews to ensure accuracy of safety information. **GMA** (NDA, label negotiation, OPDP): I have also led medical communications and publication task forces with a focus on executive management of all facets of clinical development at the time of NDA filing and transitioning to product launch plan and execution of PLP, including but not limited to publications, abstracts, manuscripts, and posters. I ensure that medical writing deliverables conform to ICH and other relevant regulatory guidelines and review TFLs.

PVRM: Managed Cardiac Toxicity associated with the IMP during ODAC and after product approval. My contributions extend to Oprozomib. These techies required the team go back. To pre-clinical experiments to elucidate the cause of bleeding. This triggered a delay in Oprozomib clinical development programs around the time when JUNO pharmaceuticals received a clinical hold from regulatory authorities. I played a leadership role in the development of Investigator Brochures for safety sections, including Reference Safety Information. Additionally, I have developed, improved, and implemented processes for signal detection and signal management and have performed services in the areas of signal detection, signal management, and benefit-risk evaluation. I stayed up to date with the latest industry practices and regulatory requirements, particularly those related to benefit/risk evaluations. Due to other priorities such as Blincyto (BTD) clinical development program in ALL, both ONYX and AMGEN decided to focus on other programs.
I have contributed to the cross-functional monitoring of pivotal post-marketing trial data My technical oversight has been invaluable to project teams, and I have contributed to project deliverables in the areas of PVRM. I have also participated in developing new presentations for internal weekly SMT, PSMT, ESMT, and external audiences (DSMB) and supported the strategic and operational functions of the business unit (PV) to meet timelines and deadlines endorsed by the department. I have worked closely with cross-functional teams during label negotiations and prior to marketing authorization.

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Abbott (Now AbbVie) – Chicago, IL 2011 - 2012

Senior Medical Director, Global Clinical Development Program Lead

Oncology, Hematology, IO

Men, Women's Health, Auto-immune Disorders

Global Pharmaceutical Research and Development (GPRD)

TAs: Oncology, Hematology, CNS, Endocrine & Metabolic Disorders, Women and Men's Health.

As a Senior Medical Director in Clinical Development Leadership at Abbott Laboratories, I was responsible for driving the strategic and technical aspects of global asset clinical development, leading clinical development efforts for multiple late-stage programs, and co-development programs with business partners in North and South America. In addition to being a key driver of clinical regulatory strategy and submission preparation, I played a critical role in developing and delivering the clinical development strategy for assets consistent with Abbott's overarching strategy and vision for global product research development and Abbott Oncology, Hematology, Endocrine and Metabolism. I was also responsible for identifying opportunities for future indications and creating a highly differentiated strategy. My role required both individual and team leadership, exceptional communication skills, and the ability to lead cross-functional teams, engage with external thought leaders, and promote a culture of innovation. Additionally, I served as the lead presenter/moderator at regulatory defense proceedings and was responsible for clearly and accurately articulating clinical strategy and clinical data, scenarios, and tactics in a way that is appropriate for the audience. Overall, my strategic and innovative thinking, strong communication skills, and leadership capabilities contributed to the success of multiple clinical programs seeking primary and supplemental regulatory approvals and/or support of approved indications.

Forest Pharmaceuticals, (Now AbbVie), NY 2009- 2011

Medical Director

Global Clinical Development Lead
CNS, Men & Women's Health, GI, Metabolic Disorders

During my tenure at FOREST laboratories, I assumed roles and responsibilities of program lead for assigned projects. I provided clinical leadership, strategic as well as daily tactical medical and scientific input for all assigned projects, monitored patients enrolled during clinical trials, and oversaw the PVRM activities of assigned investigational medicinal products. I also prepared, edited, and finalized core documents, including the study synopsis of clinical study protocols, investigator brochures, synopses, regulatory documents, and related clinical documents such as abstracts, posters, presentations, and manuscripts. Furthermore, I led the strategic planning, oversight, and management of the assigned clinical program(s) from an end-to-end clinical development perspective, led the preparation of the global Clinical Development Plan (CDP) and Clinical Trial Protocols for assigned product candidates, and organized and led scientific review boards (SRBs) for assigned products. I supervised and directed my direct reports, communicated with internal and external stakeholders, interacted with health authorities on assigned projects, monitored and reviewed medical data for clinical trials that were completed, analyzed, presented, and interpreted the data from clinical studies, led medical communications and publication task force with focus on executive management of all facets of clinical development at the time of NDA filing, and collaborated with cross-function teams, including RA, PVRM, clinical operations, data management, statistical analysis, QC, CMC, and other departments. I reviewed CRFs, draft and final datasets and TFLs, database specifications, eCRF completion guidelines, medical coding conventions, data management QC plans, data validation plans. I also composed and finalized CSRs and reviewed training slide decks for clinical sites for the next phase clinic study site's startup. Trained the staff and external teams for updates regarding safety excellence. I also held various roles and responsibilities as a program lead for assigned projects. As the global safety officer, I was tasked with monitoring incoming safety information and ensuring compliance with pre and post marketing safety reporting regulations. I was responsible for analyzing incoming safety information from phase 1 - 4 clinical studies and conducting medical reviews of ICSR narratives of reported AE/SAE/SUSAR. In addition to this, I led cross-functional meetings and provided continuous support as a safety officer, leading the safety signal management process, including detection, evaluation, and communication of additional risk minimization measures. I was heavily involved in day-to-day ICSR workflow management within drug safety systems, which included reconciling safety data with clinical development data bases and ensuring queries were sent and subject was followed-up until event resolution. Furthermore, I collaborated with cross-functional teams, such as RA, PVRM, clinical operations, data management, statistical analysis, QC, CMC, and other teams. I also led medical communications and publication task force, and contributed to clinical trial protocols, IND/NDA submissions, and Risk Management Plans. Lastly, I made recommendations to the Executive Safety Teams and trained the staff and external teams for updates regarding safety excellence.

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Neurocrine Biosciences, San Diego, CA 2007 - 2009

GnRH-a Clinical Development Program Lead

Clinical Research & Development

GnRH-antagonist program Lead

During my tenure at Neurocrine Biosciences, I had the privilege of assuming a variety of roles and responsibilities within the clinical development and safety departments. As a program lead, I was responsible for overseeing assigned projects and ensuring that they were completed within established timelines. Additionally, I assumed safety monitoring responsibilities for phase 1 and 2 clinical studies, which involved reviewing SAEs, SUSARs narratives, analyses of similar events, and ensuring that patients were followed up until event resolution.

As a core member of the clinical development team and product safety team, I monitored patients enrolled during Phase I and 2 clinical trials for two assigned products. I also participated in cross-functional monitoring of clinical study data and reviewed and updated IB, protocols, ICF, Protocol, IB, and other documents that could have been impacted by changes in CSI. Furthermore, I contributed to clinical trial protocols, IND/NDA submissions, and Risk Management Plans.

One of my key responsibilities was to assist in the preparation of aggregate reports and other safety-related documents or sections, such as DSURs, 6-month line listings, and internal safety assessment reports. I also developed materials and conducted training sessions when appropriate to a variety of audiences. Additionally, I re-reviewed SOPs, monitored interim data, discussed potential subject eligibility, and evaluated incoming safety information, ICSR & SUSAR narrative, causality assessment, and SAEs reporting.

As a safety signal management lead, I was responsible for the detection, evaluation, and communication of additional risk minimization measures. I developed, improved, and implemented processes for PVRM and contributed to clinical trial protocols, IND/NDA submissions, and Risk Management Plans. Furthermore, I led medical communications and publication task forces with a focus on executive management of all facets of clinical development at the time of NDA filing and transitioning to product launch plan and execution of PLP, including but not limited to publications, abstracts, manuscripts, posters, and promotional material review.

In addition, I collaborated with cross-functional teams such as RA, PVRM, clinical operations, data management, statistical analysis, QC, CMC, and others. I managed all aspects of outsourced or internal CSR production and ensured project delivery while adhering to relevant regulatory guidelines. Finally, I presented continuous monitoring of patient data from a safety point of view to the safety committees and led Investigator Brochure development for safety sections, including Reference Safety Information. I also developed materials and conducted training to a variety of external and internal audiences and participated in cross-functional monitoring teams.

OSI Pharmaceuticals (Now Astellas Pharma Inc.), NY 2004 - 2007

Medical Director

Clinical Research and Development, Medical Scientific Affairs

Dual Roles: Oral EGFR-inhibitor (Erlotinib) Tarceva® Programs

TA: Oncology, Solid tumors, Multiple Sclerosis, Ophthalmology, Women and Men's Health

During my time at OSI Pharmaceuticals, I held dual roles in the Clinical Development and Medical Scientific Affairs departments. As a safety officer for assigned projects, I monitored patients enrolled in Phase 1, 2, and 3 clinical trials and reviewed laboratory abnormalities, organ functions, and other vital signs. I also led co-development activities with EMD Serono, Genentech, and Roche and worked closely with cross-functional teams during label negotiations prior to marketing authorization. I contributed to the implementation of strategies to ensure patient safety and mitigate potential risks and led the design, planning, and execution of clinical trials, including surrogate biomarkers and safety endpoints. In addition, I reviewed core documents and updated them as needed, such as IBs, protocols, protocol amendments, and core safety information.

I evaluated incoming safety information, ICSR narratives, analyses of similar events, and reporting, ensuring medical review of line listings and TFLs, and timely generation of slide decks for the executive management team. I also led routine or ad-hoc literature surveillance activities and the medical communications and publication task force, with a focus on the executive management of all facets of clinical development during the NDA filing and transitioning to the product launch plan and execution of PLP, including publications, abstracts, manuscripts, posters, and promotional material content generation. Additionally, I collaborated with cross-functional teams, such as RA, PVRM, clinical operations, data

management, statistical analysis, QC, CMC, and others.

As a project manager, I completed documents according to agreed-upon timelines, followed up with study teams, and managed all aspects of outsourced or internal CSR production, ensuring project delivery. I ensured that medical writing deliverables conformed to ICH and other relevant regulatory guidelines and reviewed TFLs. I also proposed study design, composed clinical study protocols and other core documents, and ensured queries were sent and subjects were followed up until event resolution. Lastly, I examined the cellular, biochemical, and molecular processes underlying toxic responses in pre-clinical studies, attended DIA, and maintained professional PV knowledge through CMEs.

Clinical Study Site Experience (Academia)

Stanford University Medical Center 2000 – 2004

Post doctorate Fellowship in Hematology/Oncology
Molecular Targeted Therapy
Daniel Den-Hood Cancer Clinic, Erasmus MC, Rotterdam

Molecular Targeted Therapy:

- Published numerous manuscripts, abstracts
- Presented at international societies
- EGFR inhibitors
- VEGF inhibitors
- Wnt7 Pathway
- IGF family (IGF-1 and IGF-2)
- IGFBPs: IGFBP1 and IGFBP3
- PAPP-a
- Pro-MBP
- HIF-1
- Affymetrix Prognostic Tests
- Published articles during fellowship
- Experiment applying Affymetrix gene expression in preclinical research laboratory

Some of the responsibilities included:

- Diagnostic, Predictive Testing Using Biomarkers
- In vitro cell culture (fresh or post IVF granulose cells), PAPP-a and pro-MBP project
- Global gene profiling in human endometrium during the window of implantation
- Led Affymetrix gene expression analyses activities of the post-doctorate teams
- Global gene profiling in human endometrium
- Reviewed scientific publications as deputy editor. Published 3 articles in Molecular Targeted Therapy.
- ELISA and RIA techniques, FISH, Westerns blots, PCR and Hybridization, Flow Cytometry (multi-color cell analyzer)
- A list of experiments conducted, and publications can be provided upon request.

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Daniel Den-Hoed Cancer Center, Erasmus MC, Rotterdam 1994 – 2000

Research fellow & Co-Principal Investigator

Molecular Targeted Therapy, Radiolabeled Oncology, Neuroendocrine Tm, and Hematology

Sponsors: Organon, Serono Benelux, Ferring, Schering-Plough, Kendle Int, and Akzo Nobel

During my time as a Co-Principal Investigator at Daniel Den Hoed Cancer Center, EMC Rotterdam, I was responsible for overseeing a range of clinical research activities. I led first-in-human clinical studies, managed Phase 1/Phase 2 Unit clinical research activities and acted as Medical Monitor for clinical development programs in Systemic Hormone Therapies. I also played a key role in Translation Medicine activities, including preclinical to clinical transition activities, clinical development preparations, and clinical operation supportive activities. In addition, I oversaw the implementation, monitoring, and conduct of phase I, II, and III clinical trials, while providing protocol-specific scientific training to the project team. I was actively involved in preclinical experiments in Molecular Therapy, including EGFR inhibitors, VEGF inhibitors, Leptin, Wnt7, IGF family, and IGFBP. As a spokesperson and senior scientist, I led the medical program for the therapeutic area of Women's Health and Men's Health, including BPH. I established and maintained cross-functional alignment and reliable KOL interaction following participation in internal meetings and attendance at professional seminars. My work also involved composing more than 30 publications, abstracts, articles, textbooks, and a PhD book. Finally, I worked with CRO (Kendle) and performed medical monitor tasks and responsibilities, drawing on my 8 years of experience as a Co-Investigator in conducting multi-center clinical trials in targeted therapy.

Education

- 2003 Stanford University School of Medicine, Stanford, CA, Postdoctoral Fellowship
- 2002 Erasmus MC, Rotterdam, the Netherlands, PhD
- 1998 Erasmus MC, Daniel den Hoed Cancer Centre, Rotterdam, the Netherlands, Residency
- 1994 Erasmus MC, Rotterdam, the Netherlands, Gynecology & Oncology Residency
- 1994 Erasmus MC, Rotterdam, the Netherlands, MD
- 1998 Distinguished Women's Health Expert, Faculty

Affiliations

- ENDO (Endocrine Society)
- ASCO (American Society of Clinical Oncology)
- ASH (American Society of Hematology)
- EHA (European Hematology Association)
- DIA (Drug Information Association)

Languages:

- English and Dutch (Fluent and proficient)

Publications (English):

- Imani, R, ATS 2016: A Randomized, Double-Blinded, Placebo-Controlled, Ascending Dose Study of the Safety, Tolerability, and Pharmacokinetics of XmAb®7195.Poster Discussion Session
- Clinical pharmacokinetics and pharmacodynamics of ME-401, an oral, potent and selective inhibitor of phosphatidylinositol 3-kinase, following single ascending dose administration to healthy volunteers, AACR 2016: Apr 20, 2016. Ofir Moreno, Robert Imani, Pui Leung.
- Imani, R; D Thai-Cuarto; R Jimenez R, J Burke, R Kroll, C O'Brien. PETAL Study: Safety, Tolerability and effectiveness of Elagolix, an Oral GnRH antagonist for endometriosis.
- Imani, R; Jimenez, R.; Burke, J.; Akright, B.; Koltun, W.; O'Brien, C. Endometriosis Recruitment Methodology and Patient Baseline Characteristics in Clinical Trials. Endocrine Society for Human

Reproductive Endocrinology (ESHRE), Amsterdam, the Netherlands. Submitted (2009).

- O'Brien, C, Jimenez, Imani, R; R.; Burke, J.; Dmowski, WP. Elagolix, An Oral GnRH antagonist For Endometriosis, Has Minimal Impact On Bone Mineral Density. Endocrine Society's Annual Meeting (ENDO 09), Washington, DC, June 10-13, 2009.
- Imani, B; Eijkemans, MJ; te Velde, ER; Habbema, JD; Fauser, BC. Predictive value of initial screening in normogonadotropic oligoanovulatory infertility during clomiphene citrate induction of ovulation. Endocrine Society for Human Reproductive Endocrinology (ESHRE), Edinburg, UK. June 1997.
- Imani, B; Eijkemans, MJ; te Velde, ER; Habbema, JD; Fauser BC. Discrepancies in predictors of ovulation and conception following clomiphene citrate induction of ovulation in normogonadotropic oligo-amenorrheic infertility. 16th World Congress on Fertility and Sterility and the 54th Annual Meeting of the American Society for Reproductive Medicine, San Francisco, CA. October 3-9, 1998.
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- Macklon, NS; Imani, B; Fauser, BC. 1999 Optimizing protocols for ovulation induction. In: Female Infertility Therapy, current practice, Z. Shoham, C. M. Howles, H.S. Jacobs (Eds.), Martin Dunitz. Pp 75 - 83, 429 p.; ISBN 18-53175-93-5.
- Imani, B; Eijkemans, MJC; Habbema, JDF; te Velde, ER; Fauser, BC. 2002 Ovulation induction: Predictors of ovarian response and clinical outcome. In; Polycystic Ovary Syndrome. RJ Chang, A Dunaif, JJ Heindel, eds Marvcel Dekker. Marvcel Dekker. 368 p.; ISBN 08-24707-46-X.
- Imani, B 2003 Prediction of ovulation induction outcome in normogonadotropic anovulatory infertility. 150 p.; 24 cm ISBN 90-73714-39-7
- Imani, B; Eijkemans, MJ; te Velde, ER; Habbema, JD; Fauser, BC. 1998. Predictors of patients remaining anovulatory during clomiphene citrate induction of ovulation in normogonadotropic oligoamenorrheic infertility. J. Clin Endocrinol Metab. 83:2361-2365.
- Imani B; Eijkemans MJ; te Velde ER; Habbema JD; Fauser, BC. 1999. Predictors of chances to conceive in ovulatory patients during clomiphene citrate induction of ovulation in normogonadotropic oligoamenorrheic infertility. J. Clin Endocrinol Metab. 84:1617- 1622.
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Robert Imani, MD, PhD

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Executive Summary

Academia:

- **EU: EMC Rotterdam:** FIH, Early, mid, late-stage clinical trials **1994 – 2000**
- **USA Stanford University, Palo Alto:** Early and mid-stage clinical trials **2000 – 2004**

Biotechnology (Start up and mid-size companies):

- **USA:** Early-stage FIH, Phase 1 and Phase 2 clinical studies **2004 – 2011**
- **USA:** Breakthrough (BTD), PLP, Launch, Registries, Phase 4 Clinical trials **2009 – 2013**
- **USA:** Pre-IND, FIH, Phase 1, Phase 2a & 2b Clinical trials **2016 – Present**
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Large Corporations (Pharmaceuticals)

- **USA:** Phase 3 pivotal clinical studies **2011 – 2016**
- **USA:** Label, PLP, Launch, Phase 4 Clinical trials **2014 – 2016**
- **Global Studies:** Phase 3 Pivotal studies and Phase 4 Clinical trials **2016 – Present**

Robert ensures the successful and timely completion of clinical trials within time and allocated budget.

Robert has accumulated significant expertise from US and EU academic environment in pre-clinical experiments conducted in Oncology, CNS, Women and Men's Health. Robert is committed to leveraging his many skills, experience, and passion to make a positive difference in the quality of life of patients suffering from chronic debilitating conditions with high mortality and morbidity rates across different continents.

With a proven record of accomplishments in pharmaceuticals, biotech companies, and academia depicted in Robert's CV; along with approximately 2 decades of experience in the conduct of clinical trials outlined in the following pages, he is a top-quality candidate for a position in PVRM. He has developed a clear understanding of safety operation, evaluation of incoming safety information, interaction with health authorities during ad-hoc requests, current regulatory environment, ICH guidelines, and recent changes in the legislation. Robert has significantly interacted with the regulatory agencies in the US and Europe. His experience has allowed him the good fortune to develop, register, submit, gain approval, and launch novel small molecules in unmet medical needs.

As an investigator in Daniel Den-Hood Cancer Clinical, Erasmus MC Rotterdam and Stanford School of Medicine, Robert has been fortunate to be accountable and lead numerous clinical trials from academia as a key opinion leader in 90s and treat many patients suffering from various forms of cancer. Robert focused on specific targets such as "Fibroblast growth factor (FGF), Vascular endothelial growth factor (VEGF), and "Insulin-like growth factor (IGF) and other pathways mentioned below. With a MD, PhD, residency and post-doctorate degree, Robert focused on protein biochemistry, intracellular pathways, and receptors (FGF, VEGF, EGF, PI3K, ERK, IGF, WNT-7, GnRH) that were activated. He also investigated gene expression differences between disease state versus normal conditions at Stanford School of Medicine, Daniel Den-Hood Cancer Clinic and Erasmus MC, Rotterdam.

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Brand	Product	Indication	Company	IND	Ph 1	Ph2	Ph3	NDA	Ph4	BTD
NA	Multiple IMPs	Hematology	STATERO	X	X	X			X	X
KYPROLIS	Carfilzomib	RRMM	AMGEN	X	X	X	X	X	X	X
BLINCYTO*	Blinatumomab	ALL	AMGEN	X	X	X	X	X	X	X
KYPROLIS	Carfilzomib	RRMM	ONYX	X	X	X	X	X	X	X
NEXAVAR®	Sorafenib	Thyroid (DTC)	ONYX	X	X	X			X	
NBI-56418	Elagolix	Women's Health	Neurocrine	X	X	X				
ORLISSA	Elagolix	Women's Health	AbbVie			X	X			
LUPRON Depot*	Leuprolide	Women's Health	Abbott	x				X	X	
LUPRON Depot	Leuprolide	Prostate Cancer	Abbott					X	X	
LUPRON PED	Leuprolide	Pediatric	Abbott					X	X	
ANDROGEL	Testosterone Gel	Men's Health	Abbott					X	X	
LINZESS	Linaclotide	IBD	Forest	x	X	X				
TARCEVA*	Erlotinib	NSCLC	OSI			X	X		X	
TARCEVA*	Erlotinib	Pancreatic	OSI			X	X			
TARCEVA*	Erlotinib	Head Neck	OSI	X	X				X	
TARCEVA*	Erlotinib	Ovarian Cancer	OSI	X	X					
3D CNS	Medical Device	GBM	CBYON				X			
STANFORD	2001-2003	CST and ISTs	Ferring / NBI	X	X	X			X	
EMCR- EU	1991-2001	CST and ISTs	Organon	X	X	X			X	
EMCR EU	1991-2001	CST and ISTs	AkzoNobel	X	x	x			x	
EMCR EU	1991-2001	CST and ISTs	Serono	X	X	X			X	