

City of Seattle Boards & Commissions Notice of Appointment

Appointee Name:									
Thy Pham									
Board/Commission Name:		Position Title:							
Seattle Public Utilities 2018-23 Strategic	Busine	ess Plan Custo	s Plan Customer M <i>ember</i>						
Review Panel									
		Council Cor	Council Confirmation required?						
Appointment <i>OR</i> Reappoint	ment	Yes No							
Appointing Authority:	Date	Appointed:	Term	of Position: *					
Council	8/14/	2018	8/1/2	2018					
Mayor			to						
Other:			7/31/2021						
Residential Neighborhood:	ode:	e: Contact Phone No.:							
Background:									
She has lived in Seattle for 13 years, is an advocate for early childhood education and preserving									
history, and is active in the community through fundraising, teaching, volunteering, and board service									
for nonprofits in the International District including Keiro Northwest, JCCCW, Treehouse									
Authorizing Signature (original signature	e):	Appointing Signatory:							
		Lisa Herbo	Lisa Herbold						
Les li Shold		Council M	Council Member						

THY Q. PHAM

PROFESSIONAL SUMMARY:

Clinical research professional with over 18 years of product development experience in leadership roles managing and monitoring international and US clinical trials with extensive experience in oncology and complex indications.

EDUCATION:

Wesleyan University, Middletown, Connecticut Bachelor of Arts, Chemistry May 1997

PROFESSIONAL EXPERIENCE:

BILL AND MELINDA GATES FOUNDATION

Seattle, WA Nov 2014 - present

Positions Held:

Program Officer, Feb 2016-Present

Associate Program Officer, Nov 2014-Feb 2016

Operational Leadership of the Global Health Clinical Consortium

- Lead a consortium of clinical operations leaders across 14 key product development partners (PDP) to drive opportunities and solutions for efficiencies in the conduct of clinical trials in global health.
- Develop clearly defined objectives, outputs and outcomes for needsdriven initiatives and support successful implementation.
- Foster collaboration and trust amongst partners to share knowledge, leverage expertise across organizations, and identify impactful initiatives that increase efficiency and quality in the conduct of clinical trials; semiannually convene partners to enable sharing updates and networking
- Connect partners with complementary goals to explore potential new opportunities.
- Facilitate annual evaluation of preferred providers on behalf of the consortium; identify opportunities for greater provider engagement
- Coordinate and support awareness of current initiatives of the MRCT, GHN, WHO and other groups conducting trials or supporting trials in LMICs and identified as impactful for PDPs.
- Organize, facilitate, and ensure follow up on periodic Shared Training and Data Management, Lab, Preferred Provider, eLearning, and Costs and Budgets WG teleconferences and side meetings to advance group initiatives.
- Maintain SharePoint intranet and extranet sites of documents, tools and a PDP database of study pipeline, sites, and laboratories

Grant and Contracts Management

- Review, assess and approve grants and contracts in support of clinical trials and sustainability in resource-limited settings.
- Identify and enable collaboration opportunities between for-profit pharma, vendors and CROs.

- Critically review objectives, outputs and outcomes for potential new grants as well as ongoing grants.
- Ensure clear scope and accountability for contracts to clearly define near and long term objectives and work implementation.

Strategic Department Goals Management

- Engage with internal cross-functional project teams to advance product development strategic goals.
- Contribute to a larger Product Development network strategy; ensure knowledge sharing and communication across functional teams including Global Health Regulatory Team, CMC VPAN, CMC therapeutic team, and Integrated Development
- Support identification of potential CRO partners including evaluation of strengths and capabilities-based assessments
- Provide clinical trials expertise and develop an RFP and other tools to support an initiative to expand the R&D marketplace.
- Serve on an advisory committee for a Sex and Gender in Clinical Trials
 Grand Challenges initiative
- Facilitate effective issues identification and knowledge sharing for an India Clinical Trials working group.

THY Q. PHAM, LLC

Seattle, WA Feb 2014 - present

Position Held:

Consultant, Trials Management, Feb 2014-present

Consulting Core Competencies

- Strategic Planning / Implementation
- International / National Project Management
- Team Supervision / Training
- Study Budget Management
- Problem Identification / Resolution
- Risk Management
- Timeline Development / Execution
- Vendor Management
- SOP Development & Process Development
- Excellent Communication Skills
- ICH/GCP Regulatory Compliance
- Complex Indication Monitoring
- International / National Co-Monitoring
- Independent Review Charter Development
- Data Safety Monitoring Board Management
- Electronic Data Capture
- Data Monitoring / Review / Analysis

SEATTLE GENETICS

Bothell, WA Aug 2008 - Feb 2014

Positions Held:

Manager, Clinical Trials, Apr 2011-Feb 2014

Consultant, Trials Management, Aug 2008-Apr 2011

Study Execution and Management

 Assisted with the design and review of clinical trial protocols in collaboration with medical monitor, biostatistician, regulatory affairs, senior management and other relevant groups.

- Oversaw all aspects of study conduct including feasibility, investigator selection, budgets, contracts, regulatory documents and providing protocol training. Built site relationships and provide support through life of trial.
- Developed quality control program for each clinical trial and oversaw implementation. Performed co-monitoring, evaluation, initiation, and monitoring visits, as needed. Ensured staff training was adequate and documentation of training was up to date.
- Oversaw drug accountability system, and collaborated with Investigational Drug Supply Chain.
- Maintained detailed clinical trial site and clinical trial subject information via chosen clinical trial management systems (CTMS).

Project Management and Vendor Oversight

- Responsible for establishment of charters, statement of work, and training. Responsible to resolve challenges arising from vendor performance to ensure team and project goals were achieved, on time and with quality.
- Responsible for day-to-day activities of central laboratory, central pathology, and central reader. Liaised with project team, CRAs, and site personnel to address all issues.
- Responsible for operational oversight of all study vendors, including CROs. Ensured CRO's performance to the terms of contract, CFR, ICH/GCP compliance, and overall quality of work.
- Responsible to revise RFP template and prepare accompanying training documents.
- Conducted feasibility assessments for potential new study designs.

Leadership Support

- Provided mentorship and training for junior members of the clinical trial management team. Empowered and coached assigned staff to accept responsibility for their work, managed themselves and excel at their assigned projects.
- Identified and executed department and job-related process improvements and workflow efficiencies. Assumed responsibility for development and maintenance of some department SOPs or processes.
- Problem-solved clinical team personnel issues. Reviewed and revised staff project assignments as needed to balance workload.
- Assisted in the preparation and follow-up of in-house and on-site Seattle Genetics sponsored quality audits, as well as, regulatory authority inspections.
- Participated in the screening, evaluation and hiring process for assigned open clinical operations positions.

CELL THERAPEUTICS

Seattle, WA Jan 2006 - Sep 2008

Positions Held: Clinical Project Manager, Feb 2008-Sep 2008 Clinical Trials Manager, Jan 2006-Sep 2008

Team Management and Training

- Managed cross functional project teams derived from the groups within clinical development to deliver a high quality clinical trial.
- · Coordinated all training, including investigator meetings.
- Responsible for periodic clinical trial team meetings.
- Negotiated and managed competing priorities across multiple functional areas.
- Worked with functional areas on initiating, planning, executing, controlling, closing and resourcing clinical trial projects. Acted as an operational nexus or focal point for interdepartmental and intradepartmental groups (e.g. stats, data management, safety, manufacturing, regulatory), coordinating these different groups in a matrix environment to drive and complete clinical programs.
- Insured all groups provide deliverables (i.e. query generation and resolution, data base lock, study report). Informed all groups of deliverables and timeline, project developments and insures completion according to timelines.
- Selected, managed and coordinated all vendors involved in the clinical trials, e.g. central lab, insurance, CROs, including managing the RFP processes and overall budget for each; ensure vendor performance to the terms of contract, GCP/ICH adherence, and overall quality of work;
- Managed work for contract CRAs across projects
- Mentored and trained junior department members on the trial in personnel management, study management, vendor management and GCP; supervise and support career and personal development planning for direct reports; conduct performance evaluations.
- Oversaw training program preparation and administration to CROs, CRAs and site personnel.

Project Oversight and Execution

- Drove all aspects of the project management process from initiation, planning, execution, control and closure. Managed all aspects proactively.
- Responsible for creating the Project Plan.
- Responsible for creating Responsibility Table, Communication Plans and Study Data Sheet for each project.
- Developed Quality Control and Contingency Plan in conjunction with Physician and other team members in case projections fall short or quality issues develop; oversaw effective implementation.
- Reviewed actual trial conduct and quality at all levels; coordinated dayto-day activities of CRO management of clinical studies including flow of documents and information to and from sites and/or external vendors; problem-solved clinical study and personnel issues.
- Reviewed total number of queries and top queries with CDA, Protocol Lead and in-house CRA monthly.

- Developed and reviewed metrics for tracking vendor performance and study target deliverables; assessed risks and ensured effective communication within project team; reviewed performance and quality with the team and management.
- Coordinated review of Clinical Trial Master File for completeness by Clinical Monitoring and other groups.
- Prepared high-quality reports (financial, project, etc.) for management on program status and issues.
- Collaborated with Supply Chain forecast drug supply needs, planning ordering and supply to clinical sites, and ensure final drug accountability for entire project.
- Identified, evaluated and selected clinical investigators and investigative sites.

Technical Document Creation and Review

- Assisted physician in developing protocol concept sheet (study design, entry criteria and schedule of activities table). Reviewed protocol and CRFs and track them to completion.
- Ensured that a QA audit plan is developed.
- Reviewed study-related support materials created by the Monitoring and Data Management Groups (e.g. study manual, monitoring plan, ICFs, CRFs, edit check manual, data management plan, listing review process).

Budget and Timeline Development

- Created project budgets and manage cost to budgets. Developed enrollment projection, and drug supply needs as part of the budget.
- Responsible to deliver the projects on time and on budget; drove study conduct to timely completion in compliance with all regulations and SOPs.
- Informed team and management of any delay or issue with keeping the project on time.
- Created and maintained MS Project timelines for each project, and used these timelines to track and manage a project's progress.
- Created a site budget; reviewed and approved the site contract template created by legal. Reviewed and approved variations to the template.

Department and Company Initiatives

- Participated in the creation, training, and refining of departmental SOPs, working practices and training guides, standard reports, templates and forms.
- Led new hire screening, round-table discussions and hiring recommendations.

CORUS PHARMA

Seattle, WA Jun 2004 - Jan 2006

Position Held: Global Project Lead, Jun 2004 - Jan 2006

Project Management

 Reviewed Statements of Work and negotiated financial agreements with international study vendors, including central and contract laboratories, CROs, and Investigator's Meeting event planners

- Managed and assessed vendor performance and discussed performance issues with vendors and management
- Approved invoices; ensured that study expenditures remained within budgeted parameters
- Maintained timelines; tracked and reported actual against projections

Team Training and Site Management

- Addressed and coordinated responses to EC and IRB questions related to study design, entry criteria, visit procedures, statistical endpoints and analyses for 30 study centers in Australia, Canada and the U.S
- Assessed recruitment strategies to determine effectiveness of patient identification
- Managed and trained contract CRAs; prepared issues escalation strategies and addressed resolution and corrective action plans; reviewed trip reports and assessed performance through co-monitoring and weekly summaries of site activity.
- Provided mentorship and training to junior CRAs; supported career development and learning for Clinical Trial Administrators.

Facilitate Internal Communication

- Responsible to oversee internal communications within the clinical department and across other departments in the company; liaised with internal functional groups to establish timelines and assessed resources for all aspects of study conduct from start-up through closeout
- Coordinated Data Safety Monitoring Board review meetings, obtain recommendations and ensure implementation, as appropriate.

Document and Guidelines Development

- Developed protocols from concept to finalized document soliciting input from contributors and reviewers including medical directors, biostatisticians, regulatory affairs officers, data managers, and medical publishing experts; prepared template informed consent documents and reviewed site-specific informed consents for required regulatory elements.
- Created data collection guidelines to ensure that data is reported in a consistent manner.

GENENTECH

South San Francisco, CA

Jul 2002 - Jun 2004

Position Held: Consultant, Clinical Trials Manager, Jul 2002 - Jun 2004

Vendor Management

- Standardized Australia and New Zealand CRO study conduct with US operations; developed monitoring guidelines to guide CRA conduct
- Provided oversight to CRO in managing drug distribution to overseas depots
- Reviewed CRO invoices to ensure within budget and to verify work performed.
- Managed IVRS vendor and drug supply questions; communicated with various departments to resolve issues.
- Assisted internal team to reconcile CT scans for Independent Review vendor

Site Management

- Assessed site performance at 30 sites through review of trip reports and deviation summaries; provided training support and leadership to contract monitors; ensured adherence to protocols and ICH/GCP standards; served as a SAE reporting liaison between sites and the pharmacovigilance team; reviewed IRB submissions and approvals, consents, safety reports, and critical documents.
- Served as a regional monitor and primary contact for 2 local sites; reviewed patient charts and source documents and retrieved CRF data during collection intervals; wrote monitoring reports and follow up letters.
- Reviewed Trip Reports and Audit Reports; addressed corrective actions for improving study conduct; escalate site and study issues to broader project team at weekly meetings

Data Review and Reconciliation

- Created data listings review strategy with consideration of data management checks and query flow; planned review cycles for project milestones; communicated clinical needs to programmers to produce final listings programs; trained team to conduct data listings review.
- Ensured appropriateness of edit checks, query language, and prevent duplicate querying by reviewing all queries prior to issuance to sites for resolution;
- Reconciled patient consent and samples collection and processing for elective pharmacokinetics endpoint

PPD DEVELOPMENT

San Bruno, CA; Salt Lake City, UT; Philadelphia, PA Jan 1999-Jul 2002

Positions Held: Senior Clinical Research Associate, Feb 2001 - Jul 2002

Clinical Research Associate II, Feb 2000 - Feb 2001

Regional Clinical Research Associate, Jan 1999 - Feb 2000

In-house Management

- Assisted with allocation of project hours and budgets for team members; reviewed Master Action Plans, negotiated and managed timelines for sponsor deliverables; participated in bid defense meetings.
- Collected and reviewed critical documents; developed CRFs, CRF guidelines, monitoring reports, monitoring report completion guidelines.
- Identified and evaluated potential investigators from various databases;
 comonitored with and trained other CRAs on all types of monitoring visits
- Prepared documentation for SAE reporting; reviewed data tables and listings.
- Addressed drug supply issues directly with drug vendors and investigators.

Site Management

- Responsible for managing site performance; develop study forms and templates to support protocol compliance.
- Presented at investigator meetings; provided ongoing training to site staff as needed on protocol schedule and procedures.
- Conducted Qualification, Initiation, Monitoring and Close Out visits staying within established budget parameters; source verified CRFs;

- identified and escalated protocol deviations and violations and corrective action
- Resolved CRF discrepancies and/or clarifications at site visits, via telephone, or via fax as deemed appropriate for the study; performed drug accountability, ensured prompt reporting of adverse events.

ADVANCED CLINICAL RESEARCH, DRUG AND DEVICES CLINICAL SERVICES

Salt Lake City, UT Jul 1997 – Dec 1998

Position Held: Clinical Research Coordinator, Jul 1997 - Dec 1998

Patient Recruitment

- Recruited patients for participation in ongoing drug studies; tracked enrollment performance against other participating sites; evaluated eligibility and maintained patient visit schedules and relationships.
- Monitored adverse events and SAEs and triaged the appropriate action required in order to provide care for patients and ensure due diligence reporting to the sponsor.
- Developed approaches to patient recruitment and retention into studies.
- Dispensed study medication and conducted study medication accountability.

Data Collection and Reporting

- Collected study data and recorded data in source records and clinic charts; coordinated sponsor monitoring and responded to queries.
- Reviewed data recorded from devices studies involving syringes, infusion pumps and catheters; ensured data accuracy between source records and CRF.
- Coordinated evaluation of AE and efficacy data with medical doctors, nurse practitioners, and nurses.
- Ensured protocol compliance and reviewed protocol deviations and violations for training purposes.
- Identified and implemented quality improvements in study conduct with physician and study team.

THERAPEUTIC EXPERIENCE:

Colorectal Cancer (Oncology)

Hodgkin Lymphoma (Hematology-Oncology)

Non-Hodgkin Lymphoma (Hematology-Oncology)

Anaplastic Large Cell Lymphoma (Hematology-Oncology)

Diffuse Large B-cell Lymphoma (Hematology-Oncology)

Ovarian Cancer (Oncology)

Non Small Cell Lung Cancer (Oncology)

Thrombotic Microangiopathies (Hematology)

Macular Degeneration (Ophthalmology)

Cystic Fibrosis (Pulmonology)

Pnuemonia (Pulmonology)

Sinusitis (Upper Respiratory)

Hepatitis B (Hepatology and Gastroenterology)

Hormone Replacement Therapy (OB/Gyn)

Hypertension (Cardiovascular)

TRAINING AND CERTIFICATIONS:

Project Management Professional Refresher, Project Management Institute, Next Level Consulting, 2016

Project Management Professional Course, Project Management Institute, Key Consulting, 2012

Project Management Fundamentals, Project Management Institute, Key Consulting, 2006

Project Management Certification Course, Project Management Institute, Key Consulting, 2006

Project Management, Intermediate, Barnett, 2005

COMMUNITY SERVICE:

Moriguchi Family Council, Develop family employment policy, fundraising, plan education and community engagement, 2017-present.

Seattle Betsuin, Dharma School Teacher and Volunteer, Instruction for middle school students in Buddhist teachings and philosophy; fundraising, 2015-present

Phinney Neighborhood Preschool Coop, Volunteer Parent, engage parents in community building initiatives and provide advisory support for school safety, 2010-2015.

United Way of King County, Multilingual Tax Preparer, prepare federal taxes for Seattle residents, an initiative that supports the 10 year plan to end homelessness in King County, 2007-2009.

Seattle Keiro Fundraiser, Live Auction Co-Chair, raised funds to support the needs of the retirement/assisted living facility, July-October 2005

San Francisco Suicide Prevention, Counselor, received crisis line calls, triaged as needed to local law enforcement and other community resources/programs, 2003-2004

LANGUAGES:

Fluent in reading, writing, and speaking English and Vietnamese Beginner knowledge of Japanese and French

Seattle Public Utilities 2018-2023 Strategic Plan Update Customer Review Panel

11 Members: Pursuant to Res 31825, all members subject to City Council confirmation, 3-year terms:

- 5 City Council-appointed
- 6 Mayor-appointed
- # Other Appointing Authority-appointed (specify):

Roster:

*D	**G	RD	Position No.	Position Title	Name	Term Begin Date	Term End Date	Term #	Appointed By
6	6 F 7 1. Member		Member	Jessa Timmer	8/1/18	7/31/2020	1	Mayor	
~	М		2.	Member	Kyle Stetler	8/1/18	7/31/2020	1	Council
6	М	4	3.	Member	Dave Layton	8/1/18	7/31/2020	1	Mayor
	F		4.	Member	Suzanne Burke	8/1/18	7/31/2020	1	Council
	F		5.	Member	Maria McDaniel	8/1/18	7/31/2020	1	Mayor
	F		6.	Member	Laura Lippman	8/1/18	7/31/2021	1	Council
6	М	7	7.	Member	Bobby Coleman	8/1/18	7/31/2021	1	Mayor
	M		8.	Member	Noel Miller	8/1/18	7/31/2021	1	Council
	F	6	9.	Member	Puja Shaw	8/1/18	7/31/2021	1	Mayor
	F		10.	Member	Thy Pham	8/1/18	7/31/2021	1	Council
6	М	N/A	11.	Member	Rodney Schauf	8/1/18	7/31/2021	1	Mayor

SELF-IDENTIFIED DIVERSITY CHART					(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
	Male	Female	Transgender	NB/O/U	Asian	Black/ African American	Hispanic/ Latino	American Indian/ Alaska Native	Other	Caucasian/ Non- Hispanic	Pacific Islander	Middle Eastern	Multiracial
Mayor	3	3											
Council	2	3											
Other											Provided management of the control o		
Total	5	6											

Key:

- *D List the corresponding *Diversity Chart* number (1 through 9)
- **G List gender, M= Male, F= Female, T= Transgender, NB= Non-Binary O= Other U= Unknown
- RD Residential Council District number 1 through 7 or N/A

Diversity information is self-identified and is voluntary.