

Ramses Fouad Sadek, PhD

Augusta University, Georgia Cancer Center
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Overview:

Extensive research experience in the areas of drug development, oncology, diagnostics devices, HIV, vaccine, generic bioequivalence, health disparity, and precision studies with over 230 protocols. Well-established records and accomplishments in observational studies, notational datasets analysis, and clinical trials design, analysis, and submission with FDA interaction. Experience in academia, industry, government, non-for-profit organization with multidisciplinary sittings and staff and project management. In addition to the management and leadership history, I have an extensive experience as individual contributor in design and analysis of several areas of, clinical trials, SAS programming, patient reported outcomes, health economics, quality of life assessment, public health and Epidemiology with co-authorships in leading professional journals. Professional activities include a full professor in a medical college, adjunct faculty positions, and professional journals editor. Member of several scientific organizations and invited speaker in several meetings. Love challenge and enjoy building teams, mentor staff, and add significant value to research.

EDUCATION

- PhD. (Statistics & Educational Psychology), University of Georgia (Athens, Georgia), 1992
- M.S., Applied Statistics, University of Georgia (Athens, Georgia), 1989
- Ph.D. graduate coursework, Math Department, Clemson University (Clemson, SC), 1987-1988
- M.Sc., Mathematical Statistics, Cairo University (Cairo, Egypt), 1983
- B.S., Statistics, Cairo University (Cairo, Egypt), 1980
- Certificate, Burden of Disease Assessment Program, Harvard University (Cambridge, MA), 1999

PROFESSIONAL EXPERIENCE

2013-Present

Professor of Biostatistics, department of Population Health Science & director of Biostatistics core, Georgia Cancer Center, Medical College, Augusta University, Augusta, GA.

- Member, Georgia Cancer Center.
- Elected member, Faculty senate.
- Serve as a member at the university governance committee.
- Serve on Protocol Review and Monitoring Committee (PRMC).
- Hold responsibility for the efficient functioning of the Cancer Center Biostatistics Core to ensure that deliverables of high quality are produced within the planned timelines.
- Lead operational activities of the Clinical trials Biostatistics functions such as, protocol development, study design, statistical analysis plan, randomization, & data analysis.
- Consult with Principle investigators, project teams, sponsors, and U.S. Food and Drug Administration (FDA), and Cooperative groups on study-related issues
- Lead in a multi-disciplinary team setting for protocol development, data mining, observational, and longitudinal studies.
- Organize training on the use of national database systems such as SEER.
- Keep active membership in the Protocol Review and Monitoring Committee: review and evaluate protocol and provide expert opinions.
- Communicate with experts and regulatory agencies (e.g., FDA and European Medicines Agency, CDC, NIH), as needed.
- Teach graduate and service biostatistics and clinical trial classes.

- Participate in Cancer Center publication, activity planning, and resource building.
- Serve as Co-PI on several funded studies.
- Data Monitoring Safety Board for Indoximod Clinical Trials for NewLink Genetics Inc. and several studies (Augusta University and CDC)
- Lead the collaborative work for Phase I and Phase II study with Merck, NewLink genetics, AstraZeneca, and other pharmaceutical and biotech companies.

2009 - 2012

Global Senior Director, Biostatistics and Data Management, BioMerieux Inc. (Durham, North Carolina)

- Held overall responsibility for statistical aspects of clinical study design, algorithm development, and data mining
- Managed global statistics and data management groups, Electronic Data Capture (EDC) vendor and external consultants
- Served as Primary Lead for data analysis and reporting for filing and submissions
- Mentored biomathematicians and statisticians performing analyses of laboratory, biomarker data and clinical trial design and analysis
- Provided training, workshops, seminars, and presentations on statistical methods related to sampling, design, and analysis of clinical research and lab data
- Provided primary inputs for design of several PMAs and 510ks protocols and statistical analysis plans
- Planned and organized training for the Clinical Affairs and Biostatistics departments
- Provided tutorial on quality-of-life (QoL) assessment and patient reported outcomes, sample size considerations, design and writing Statistical Analysis Plans (SAP)
- Ensured compliance of statistics and data management processes with Clinical and Laboratory Standards Institute (CLSI) and U.S. Food and Drug Administration (FDA) regulations
- Oversaw implementation of EDC (changed the manual DM to EDC system)
- Established data management system specifications and Standard Operating Procedures (SOP) for statistics and data management activities
- Held responsibility for validity and integrity of data management and analyses, reporting and publications
- Oversaw publication of clinical trial results
- Ensured that clinical protocols were up to state-of-the-art standards and met all regulatory guidelines.

2008 - 2009

Vice President, Biometrics, New England Research Institute (Watertown, Massachusetts)¹

- Reorganized the Statistics and Data Management Department to meet industry standards
- Worked as Co-Principal Investigator (data center) for three sickle-cell disease clinical trials (research funded by National Institutes of Health).

2007 - 2008

Senior Director, Biostatistics and Data Management Center, Radiation Therapy Oncology Group (RTOG)² (Philadelphia, Pennsylvania)

- Held overall responsibility for operations of the RTOG Biostatistics and Data

¹ Industry consulting; part-time while working at CDC

² On leave from the CDC

Management Center

- Reviewed overall work plan within each disease site team (Head and Neck, Sarcoma, Lung, Genitourinary, Gastrointestinal, Breast, Gynecological, and Brain) with directors of statistics and data management and the team leaders to set mutual priorities
- Served as Team Leader for the Lung studies, with responsibilities that included study design, protocol development, regulatory issues, analysis and manuscripts
- Led efforts for adaptive design for Small Cell Lung Cancer studies that included seamless Phase I/II study and pharmacologically guided designs
- Monitored progress of unpublished studies and prepared periodic reports
- Collaborated with committee members to review appropriateness of authorship lines and participated in evaluation and approval of all proposed secondary analyses
- Worked with Directors of Statistics and Data Management to establish SOPs for all Statistics and Data Management functions
- Served on Executive, Research Strategy, Steering, Publications, and Membership Committees
- Oversaw the cataloguing of abstracts and manuscripts in headquarters, and regularly interacted with the Vice-Chair for Publications
- Represented RTOG on the Cooperative Group Statistical Committee
- Oversaw preparation of interim statistical reports for several studies for semi-annual RTOG meetings; collaborated with the Chair of the RTOG Data Monitoring Committee to develop the agenda for its semi-annual meeting and oversaw preparation and distribution of all necessary analyses and study materials to committee members.

2004 - Current

Consultant, New World Regulatory Solutions (Falls River, New Jersey) ¹

- Provided study design, statistics support, FDA interaction, and data analysis for clinical and device trials. Performed statistical analyses for a Toxicological studies as needed.
- **Consultant Statistician, Chembio Diagnostic Systems Inc.** (Medford, NY)
Provide design analysis for laboratory precision studies.

2005 - 2007

Consultant, Oxford Immunotec (London, U.K.) ¹

- Provided study design, statistics support, FDA interaction, and data analysis for clinical and device trials.

2001 - 2008

Team Leader: Epidemiology Branch Statistics Team, Division of HIV/AIDS Prevention, Centers for Disease Control and Prevention (CDC) (Atlanta, Georgia)

- Provided expert design and analysis of epidemiological studies and clinical trials
- Directed the statistical activities and led a team of seven statisticians
- Led protocol development of domestic and international clinical trials and interventions (over 12 trials, with many in cooperation with Gilead Sciences); examples:
 - Phase II Extended Safety Study of Tenofovir Disoproxil Fumarate (TDF) among HIV-1 Negative Men
 - Study of the Safety and Efficacy of Daily Tenofovir to Prevent HIV Infection Among Injection Drug Users in Bangkok, Thailand (Bangkok Tenofovir Study)
 - Phase II/III Trial to Study the Safety and Efficacy of Truvada Intermittent Pre Exposure Prophylaxis (iPrEP) to Prevent HIV Infection among Men Who Have Sex with Men (MSM) in Bangkok, Thailand (The iPrEP Study) Thailand
- Served as Lead Statistician on several observational and epidemiological studies; examples are:
 - Efficacy of brief case management intervention for newly diagnosed HIV-infected

- Mother-to-child transmission in a breast-feeding population in Cote d'Ivoire.
- Handling missing data in HIV research
- Led the statistical data mining efforts for HIV mother-to child transmission data
- Provided consultations on methodology, design, power and sample size, interpretations, regulatory issues; wrote SAPs for studies; wrote and reviewed manuscripts; provided input in clearance for manuscripts, and led educational activities
- Participated in several professional activities (e.g., edited manuscripts for MMWR publications, presented CDC studies at IOM, planning committee member for CDC applied statistics symposium, reviewed papers for statistical science awards, and CDC statistical advisory group, member of DMSB and serve as Guest Editor for *Statistics in Medicine*, Editor for *Drug Information Journal*)
- Collaborated on CDC-wide studies.

1999 - 2001

Team Leader: National Immunization Program, Centers for Disease Control and Prevention (CDC) (Atlanta, Georgia)

- Served as Team Leader (Anthrax and Vaccine Adverse Events Reporting System)
- Coordinated and managed several activities related to Vaccine Adverse Events Reporting System (VAERS) and anthrax research, including clinical trials for safety and efficacy of anthrax, vaccine health care centers
- Led efforts on data mining for VAERS and anthrax in addition to QoL assessment
- Managed team of nine professionals; served as the division contact person with Department of Defense (DoD), FDA, and the National Center for Infectious Diseases (NCID)
- Supervised analytical, epidemiological, and data management activities
- Developed protocols and Case Report Forms (CRF)
- Evaluated resource needs including data management, systems, and manpower
- Wrote SAPs; participated in study designs; initiated research projects, and reviewed manuscripts
- Worked on health economics project with burden of diseases assessment .

1997 - 1999

Senior Biostatistician, Mallinckrodt Inc. (St. Louis, Missouri)

- Provided study designs and SAPs for several diagnostic-imaging trials
- Worked on two bioequivalence trials that were approved (Flauxtine and Mythelphinidate)
- Designed and reviewed protocols and CRFs
Reviewed literature
- Participated in New Drug Applications (NDA) and Abbreviated NDA (ANDA) submissions; represented company at FDA meetings for two ANDAs and two NDAs
- Performed sample size and power calculations
- Provided statistical and epidemiological support for medical regulatory and other departments
- Created and modified SAS® macros and programs for safety and efficacy analyses of clinical trials, and statistical analyses for bioequivalence studies
- Interpreted statistical results and write statistical reports
- Performed pharmacokinetic (PK) parameters estimation and dose response analysis, shelf-life estimation, and stability analyses.

1994 - 1997

Epidemiologist, National Center for Infectious Diseases, CDC (Atlanta, Georgia)

- Provided data modeling, programming, survival analysis, data analysis statistical consultation and interpretation for several epidemiological studies including Ebola,

Lassa Fever, CCHF, and Hantavirus outbreaks:

- Blood transfusion effect on Ebola infected persons
- Density estimates and assessment of marking methods for dog population during rabies vaccination campaign in Philippines
- Implications for surveillance of global emerging viral hemorrhagic fevers
- Epidemiology of rodent bites and rat infestation in New York
- Presented findings in professional meetings and peer-reviewed journal publications
- Applied extensive use of SAS® and SPSS
- Provided statistics training for EIS officers
- Published results in the Journal of Infectious Diseases, American Journal of Epidemiology, Review of Veterinary Medicine, Journal of Virology, American Journal of Tropical Medicine and Hygiene, and several other publications.

1994 - 1996;
1989 - 1992

Instructor/Teaching Assistant, Adjunct Faculty, University of Georgia, Educational Psychology Department

- Taught graduate courses in statistics, as well as several undergraduate and graduate courses and assisted faculty and graduate students in their research; classes included research methods, multivariate analyses, and regression methods.

1992 - 1994

Assistant Professor, Cairo University, Department of Statistics (Cairo, Egypt)

- Supervised graduate students research (one Ph.D. and two Master)
- Taught graduate and undergraduate courses including: Intro to Mathematical Statistics; Multivariate Methods; Statistical Computations and Programming; Research Methods; Probability; Testing of Statistical Hypotheses
- Supervised student activities, conducted seminars, and published papers.

1980 – 1986

Instructor, Cairo University, Department of Statistics (Cairo, Egypt)

- Taught undergraduate statistics and mathematics classes

1998-Present

Other Professional Activity (Non-Paid / Volunteer)

- Faculty, Programs to increase Diversity among individuals engaged in health-related research (PRIDE). Teaching Biostatistics, for clinical research, clinical trials and study design (2013-Present).
- DSMB member: Indoximod studies, NEWlink Genetics.
- Grant Review Panel member: for grant submitted from PRIDE faculty (2017).
- Invited speaker, Interim Analysis Symposium, Philadelphia, PA (March 2017).
- Adjunct Professor, Department of Biostatistics, Georgia Southern University, College of Public Health (2006-present)
- Adjunct Professor, Department of Biostatistics and Epidemiology, University of Pennsylvania, School of Medicine (2007-2009)
- Editorial Board Member, Drug Information Journal, (2004-Present)
- DSMB: Global AIDS Program / HIV Clinical Trial (2008-2010)
- CDC Statistical Advisory Group (1999-2005)
- CDC Statistical Science Award Committee (2000-2007)
- CDC Symposium Planning Committee (2000-2007)
- Invited Speaker, Biopharmaceutical Applied Statistics Symposium (few times)

TOOLS/SKILLS

- Microsoft Office (Word, Excel, PowerPoint, Access, Outlook)
- SAS, STATA, SPSS, nQuery, PASS, , NCSS, SEER*stat

PROFESSIONAL AFFILIATIONS

EDITORIAL BOARD MEMBERSHIPS

- 2004- Present Therapeutic Innovation and Regulatory Sciences Journal.
- 2018-Present Clinical Trials and Drug Interactions Journal.
- 2019-Present Journal of HIV and AIDS Research
- 2018-Present JOURNAL OF EMERGENCY MEDICINE AND PRIMARY CARE
- 2018- Present *Annals of Biostatistics & Biometric Applications.*
- 2018-Present The British Medical Journal
- 2017-Present *Biostatistics and Epidemiology International Journal*
- 2018-Present *Scientific Journal of Biometric and Biostatistics* (Honorable Editor)
- 2018-Present Health and Medical Informatics Open Access

DSMB membership

- NewLink Genetics: Indoximod Clinical Trials
- CDC: Special Pathogens Studies
- CDC: HIV Pediatric Study
- Augusta University CC-16047 Clinical Trial,

Other services and memberships

- Member: Augusta University Faculty Senate
- Member: Augusta University Governance and communication committee
- Georgia Cancer Center: Protocol Review and monitoring committee (PRMC)
- Panelist: Good Clinical Practice document, FDA, Academia, Industry
- Minority PRIDE program Faculty member
- Panelist: R01 Grant Review for PRIDE fellows
- American Association of Cancer Research (AACR)
- American Society for Clinical Oncology (ASCO)
- American Society of Hematology (ASH)
- Biometric Society, Eastern North American Region (ENAR)
- American Statistical Association (ASA)
- Society for Clinical Trials (SCT)
- Drug Information Association (DIA)

HONORS AND AWARDS

- Georgia Cancer Center: Outstanding Service in the Cancer Center educational program. April, 2015
- American College of Radiology (ACR): Outstanding Team Work, 2008
- CDC, Statistical Advisory Group: Services to the CDC Applied Statistical Symposium and Statistical Research throughout CDC, 2007
- CDC, National Center for HIV/AIDS Prevention: Special Performance Award, for Organizing Educational Activities And Mentoring Staff for Epidemiology Branch May, 2003
- CDC, National Immunization Program (NIP):, Special Performance/Act Award for Leading Collaborative Effort between NIP, NCID, and DoD to Identify and Coordinate Anthrax Research, 2001
- CDC, EPO, performance award, for improving the quality of scientific research and leading research on Global Burden of Disease, 2000

- Mallinckrodt Inc., Performance Award in Recognition for Contribution to the Methyl in Product Launch & Team Leadership, 1999

GRANTS:

Old Grant:

5U10CA032115-26: "Radiation Therapy Oncology Group Statistical Center, American College of Radiology". 20Feb07-31Dec08. Total funding \$1,038,338

R01CA142840 (Kong): Title: Functional Image and Molecular Marker to Individualize Adaptive Radiation Doses. 05/01/10-04/30/15. 0.6 calendar months

Current Grants:

(PI: Yukai He) R01- TCR engineering of human T cells for immunotherapy of hepatocellular carcinoma.

(PI: Munn) R35- Driving immunogenic cross-presentation in the tumor microenvironment

(PI: Munn): R01- Chemo-radio-immunotherapy for pediatric brain tumors

SELECTED PUBLICATIONS

- Nagy Youssef, Dheeraj Ravilla , Cherishma Patel , Mark Yassa , Ramses Sadek , Li Fang Zhang, Laryssa McCloud, William V. McCall and Peter B. Rosenquist (2019). Magnitude of Reduction and Speed of Remission of Suicidality for Low Amplitude Seizure Therapy (LAP-ST) Compared to Standard Right Unilateral Electroconvulsive Therapy: A Pilot Double-Blinded Randomized Clinical Trial. *Brain Sci.* (2019) 9(5), 99. <https://www.mdpi.com/2076-3425/9/5/99/pdf>
- Chung JM, Simmerman EL, Sadek RF, Wojtowicz S, Dillard TA, Albo D, Thomson NB, Schroeder C (2019) Financial Analysis of Free Lung Cancer Screening Program Shows Profitability Using Broader NCCN Guidelines. *Ann Thorac Surg.* 2019 Mar;107(3):885-890.
- Anh Thu Nguyen, Ashwin, Ajith, Vera Dobos, Daniel Horuzsko, Ali Arbab, Ramses Sadek, Anatolij Horuzsko. The Innate immune receptor TREM-1 promotes liver injury and fibrosis. Submitted to the *Journal of clinical investigation* (2018).
- Schroeder C, Chung JM, Simmerman E, Sadek R, Wojtowicz S, Dillard T, Albo D, Thomson. Financial analysis of a free lung cancer screening program shows profitability despite applying broader National Comprehensive Cancer Network Guidelines" and submitted to the *Annals of Thoracic Surgery*. 2018.
- El Osta B, Hu F, **Sadek R**, Chintalapally R and Tang S (2017): Not all immune-checkpoint inhibitors are not created equal: Meta-analysis and systemic review of immune-related adverse events in cancer trials. *Critical Reviews in Oncology / Hematology*(2017) 119, 1-12 (<http://dx.doi.org/10.1016/j.critrevonc.2017.09.002>).
- Nayak-Kapoor A, Hao Z, **Sadek R**, Dobbins R, Marshall L, Vahanian N, Ramsey W, Kennedy E, Mautino M, Link C, Lin R, Royer-Joo S, Liang X, Morrissey K, Mahrus S, McCall B, Pirzkall A, Munn D, Janik J, Khleif S. (2017) Phase Ia Study of the Indoleamine 2,3-dioxygenase 1 (IDO1) Inhibitor Navoximod (GDC-0919) in Patients with Recurrent Advanced Solid Tumors. Submitted to *AACR journal*.
- Pyrzak A, Fambrough J, Hu F, Rungruang BJ, **Sadek R**, Macfee MS and Ghamande S (2017): Efficacy of levonorgestrel intrauterine device (LIUD) and transvaginal ultrasound (TVUS) as treatment and surveillance of women with early endometrial cancer (EC) and complex atypical hyperplasia (CAH) who are poor surgical candidates. In progress.
- Simmerman E, Thomson N, Dillard T, Hao Z, **Sadek R**, Khleif S, Schroeder C (2017). Free lung cancer screening trends towards a twofold increase in lung cancer prevalence in the underserved Southeastern United States. *Southern Medical Journal* Vol 110, Number 3, 188-194.
- Zhao J, Xia Y, Kaminski J, Hao Z, Mott F, Campbell J, **Sadek R**, Kong FM (2016). Treatment-Related Death during Concurrent Chemoradiotherapy for Locally Advanced Non-Small Cell Lung Cancer: A Meta-Analysis of Randomized Studies.. *PLoS One.* 11(6):e0157455. doi: 0.1371/ journal.pone.0157455. eCollection 2016. PMID:27300551
- Jin JY, Wang W, Ten Haken RK, Chen J, Bi N, **Sadek R**, Zhang H, Lawrence TS, Kong FM (2015). Use a survival model to correlate single-nucleotide polymorphisms of DNA repair

- genes with radiation dose-response in patients with non-small cell lung cancer. *Radiother Oncol.* 117(1):77-82. doi: 10.1016/j.radonc.2015.07.024. Epub 2015 Aug 4. PMID:6253951
- Campbell J, Zhao J, Zaenger D, Colton L, Madi R, Dasher B, Ferguson C, Lewis R, Smith A, **Sadek R**, Terris M, Kong F (2015). No Significant Difference in Overall Survival between Caucasian and African Americans Patient with Prostate Cancer: An Analysis of 1338 Patients from a Single Institution. *International journal of radiation oncology, biology, physics* 93(3):E244 ·
 - Zakharia, Y, Colman H, Mott F, Lukas R, Vahanian N, Link C, Kennedy E, **Sadek R**, Munn D, Rixe, O.(2015).Updates on phase 1b/2 combination study of the IDO pathway inhibitor indoximod with temozolomide –refractory primary malignant brain tumors. *Neuro-Oncology* 17:vol107-v112. Doi:10.1093/neuonc/nov218.21
 - Wang S, Stenmark M, **Sadek R**, Campbell J, Stanton P, Zhao J, Matuszak M, Ten Haken, Kong F (2015). A Novel Radiation Esophagitis Predictive Model with IL-8, Dosimetric and Clinical Factors for Non-Small Cell Lung Cancer Patients. *International Journal of Radiation Oncology. Volume 93.3 Supplement.* DOI: 07.1643
 - Jin J, Wang W, Bi N, Haken T, Schipper M, **Sadek R**, Zhang H, Lawrence T, Kong F (2014). A blood biomarker dependent survival model for NSCLG patients treated with radiation therapy: locally advanced non-small cell lung cancer. *International Journal of Oncology Vol 90.5*, DOI: 10.1016/j.ijrobp.2014.08.168
 - Kong F, Campbell J, Stanton P, Stenmark M, Zhao J, **Sadek R**, Lawrence T (2014) Immunomodulating Cytokines may improve overall survival prediction after radiation therapy in patients with locally advanced non-small cell lung cancer. *International Journal of Oncology Vol 90.1*, S669-670. DOI: 05.1971.
 - Nayak A, Hao, Z, **Sadek R**, Vahanian N, Ramsey W, Kennedy E, Mautino M, Link, C, Bourbo P, Dobbins R, Adams K, Diamond A, Marshal L, Munn D, Janik J, Khleif S (2014). A phase I study of NLG919 for adult patients recurrent advanced solid tumors. *J Immunother Cancer: 2(Suppl. 3): P250.* Doi: 10.1186/2051-1426-2-s3-P250. PMID:PMC4292544
 - Zakharia Y, Johnson T, Colman H, Vahanian N, Link C, Kennedy E, **Sadek R**, Knng FM, Vender J, Munn D, Rixe O (2014). PhaseI/II study of the combination of indoximod and temozolomide for adult patients with temozolomide –refractory primary malignant brain tumors. *Neuro Oncol.* 16(Suppl 5):v117-v118. Doi:10.1093/neuonc/nou258.34 PMID:PMC4218254
 - Sansom S, Harris N, **Sadek R**, Lampe M, Ruffo M, Fowler M (2007). Towards elimination of perinatal human immunodeficiency virus transmission in United States: effectiveness of funded prevention programs.1999-2001. *Am J Obstet Gynecol; 197(2 Suppl):S90-5.* PMID: 17825655
 - Yassin A, Favorov M, Maes E, **Sadek, R**, Jumaguova a, Merker V, Surdina , and Chorba T. (2005). Cost-analysis of different management policies for patients with mild hepatitis A virus infection in Kazakhstan. *Cost Effectiveness and Resource Allocation.*2005; 3:4. PMID:15890070, PMC11173129
 - Gardner, Lytt I; Metsch, Lisa R b; Anderson-Mahoney, **Sadek, R f**; Pamela c; Loughlin, Anita M d; Rio, Carlos del e; Strathdee, Steffanie d; Sansom, Stephanie L a; Siegal, Harvey A f,+; Greenberg, Alan E a (2005). Efficacy of a brief case management intervention to link recently diagnosed HIV-infected persons to care. *AIDS.* 19(4):423-431
 - Jamieson DJ, Sibailly TS, **Sadek R**, Roels TH, Ekpini ER, Boni-Ouattara E, Karon JM, Nkengasong J, Greenberg AE, Wiktor SZ (2003). HIV-1 viral load and other risk factors for mother-to-child transmission of HIV-1 in a breast-feeding population in Cote d'Ivoire. *Journal of Acquired Immune Deficiency Syndrome; 34:* 430-436. PMID: 14615662
 - Dominguez K, Lindegren M, d'Almada P, Peters V, **Sadek R**, Frederick T, Rakusan T, Ortiz I, Hsu H, Melville S (2003). Increasing trend of Caesarean deliveries in HIV-infected women in the United States, 1994-2000. *Journal of Acquired Immune Deficiency Syndromes.* Vol.33. No. 2, pp 232-8. PMID: 12794560
 - Krawczyk, C, Gardner, L, Wang J, **Sadek, R**, Loughlin A, Anderson-Mahoney P, Metsch L, Green S (2003). Test-retest reliability of a complex HIV research questionnaire administered by an audio computer assisted self-interviewing (ACASI) system. *J. Medical Care.* Vol. 41, No. 7, pp. 853-858. PMID:12835609

- Gardner L, Klein R, Szczeck L, Phelps R, Tashima K, Rompalo A, Schuman P, **Sadek R**, Tong T, Greenberg A, Holmberg S. (2003). Rates and risk for condition-specific hospitalization in HIV-infected and uninfected women. *J Acquir Immune Defic Syndr.* 1;34(3):320-30. PMID: 14600579
- Samuelson J, Buehler J, Norris D, **Sadek R**. (2002). Maternal characteristics associated with place of delivery and neonatal mortality rates among very-low-birthweight infants, Georgia. *Pediatric Perinat Epidemiol*; 16(4):305-13. PMID:12445146
- Institute of Medicine (US) Committee to Review the CDC Anthrax Vaccine Safety and Efficacy Research Program. Washington (DC): An Assessment of the CDC Anthrax Vaccine Safety and Efficacy Research Program. National Academies Press (US); 2002.
- **Sadek R**, Khan A, Stevens G, Ksiazek T, & Peters C (1999). Ebola Hemorrhagic Fever, Democratic Republic of Congo, 1995: Determinant of Survivals." *The Journal of Infectious Diseases*; 19(Suppl1): S24-7. PMID: 9988161
- Chapman LE, Mertz GJ, Peters CJ, Jolson HM, Khan AS, Ksiazek TG, Koster FT, Baum KF, Rollin PE, Pavia AT, Holman RC, Christenson JC,, Robin PJ, Behram RE, Bell LJ, Simpson GL, **Sadek RF**. Intravenous ribavirin for hantavirus pulmonary syndrome: Safety and tolerance during 1 year of open-label experience. *Antivir Ther.* 1999;4(4):211-9. PMID 107233500
 - Childs J, Robinson L, **Sadek R**, Madden A, Miranda M, Miranda L(1998). Density estimates of rural dog population and assessment of marking methods during a rabies vaccination campaign in Philippines. *Prev Vet Med.*; 33(1-4):207-18.PMID:9500175
 - Childs JE, McLafferty SL, **Sadek RF**, Miller GL, Khan AS, DuPree ER, Advani R, Mills JN, Glass GE (1998). Epidemiology of rodent bites and prediction of rat infestation in New York City. *Am J Epidemiol.* 1;148(1):78-87. PMID: 966340
 - Khan, AS, Maupin GO, Rollin PE, Noor AM, Shurie HH, Shalabi AG, Wasef S, Haddad Y, **Sadek RF**, Ijaz K, Peters CJ, Ksiazek TG (1997). An outbreak of Crimean-Congo hemorrhagic fever in the united Arab Emirates,1994-1995. *Am J Trop Med Hyg*; 57(5):519-25. PMID: 9392589
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 - **Sadek R**. (1994). Correlation Coefficient as a Goodness-of-Fit Test for Logistic Distribution. *The Egyptian Statistical Journal*, Vol. (38), No. 1.
 - Iskander M, **Sadek R** (1994). Applying Multivariate Regression Techniques in Public Opinion Polls in Egypt (in Arabic). *The National Social Review*, Cairo. Vol. 2: 109-121.
 - Selim Z, **Sadek R** (1994). A Proposed Transformation to Symmetry for Variables With Bounded Support. *Proceedings of the 6th annual conference on Statistics and Computer Modeling in Human & Social Sciences*, Faculty of Economics & Political Sciences, Cairo University.
 - **Sadek R**, Huberty C. (1994). Using Monte Carlo Studies in Discriminant Analysis: An Overview. *Proceedings of the annual meeting of the American Educational Research Association* (New Orleans, LA, April 4-8, 1994).
 - Sadek R. (1993). Outlier Detection in Classification Analysis: An Overview. *The Egyptian Statistical J.* 37(2), 222:237.

Others with acknowledgements

- Fowler T, (Consultant R Sadek), (2011). Procalcitonin for Triage of Patients with Respiratory Tract Symptoms: A Case Study in the Trial Design Process for Approval of a New Diagnostic Test for Lower Respiratory Tract Infections. *Clin Infect Dis* 52 (Suppl 4) 351-356.
- Anthony M, Gardner L et al., (consultant Sadek R), (2007) Factors associated with use of HIV primary care among persons recently diagnosed with HIV: Examination of variables from the behavioral model of health-care utilization. *AIDS Care* 19(2). 195-202.
- Marks G, et al. (consultant Sadek R(2005) Meta-Analysis of High-Risk Sexual Behavior in Persons Aware and Unaware They are Infected With HIV in the United States: Implications for HIV Prevention Programs. *J Acquir Immune Defic Syndr* , Volume 39, Number 4, 446-453.

- Rudy E, et al (consultant R Sadek). (1995). Perceptions of Human Immunodeficiency Virus (HIV) Testing Services among HIV-Positive Persons Not in Medical Care. Sexually Transmitted Diseases: April 2005 - Volume 32 - Issue 4 - pp 207-213.

ABSTRACTS:

- Theodore Johnson, **Ramses Sadek**, et al.; Phase 1b Clinical Trial of radio-chemo-immunotherapy for newly diagnosed pediatric Diffuse Intrinsic Pontine Glioma (DPIG) and advanced recurrent pediatric brain tumors using IDO pathway inhibitor indoximod. ASCO annual meeting, 2018.
- Theodore Johnson, **Ramses Sadek**, et al.; Front-line therapy of DPIG using IDO pathway inhibitor indoximod in combination with radiation and chemotherapy IDO-based therapy for DPIG. AACR Annual meeting, 2018
- Wonsuk Yoo, Karen Singh, Yommi Chung, **Ramses Sadek**. Patterns and Disparities in breast Cancer mortality trends in US states, 2000-2015, SEER data. APHA, 2017.
- A. Pyrzak, K.B. Patel, H. Williams, H. Coste, L.F. Zhang, **R. Sadek**, J.J. Wallbillich, S. Ghamande and B.J. Rungruang. "Clinical trial participation may improve survival in patients with advanced epithelial ovarian, fallopian, and peritoneal malignancies". (SGO 2017).
- K.B. Patel, A. Pyrzak, H. Williams, H. Coste, L.F. Zhang, **R. Sadek**, J.J. Wallbillich, S. Ghamande and B.J. Rungruang: "Participation in clinical trials may overcome health disparities in the treatment of advanced or recurrent epithelial ovarian cancer. (SGO 2017).
- Theodore Johnson, Dolly Aguilera, Ahmad Al-Basheer, Raven Cooksey, Bree Eaton, Natia Esiashvili, Selim Firat, John Fiveash, Nicholas Foreman, Diana Fridlyand, Gregory Friedman, Cole Giller, David Grosshans, Ian Heger, Michael Kelly, Eugene Kennedy, Jeffrey Knipstein, Ravindra Kolhe, Arthur Liu, William Martin, Waleed Mourad, Rafal Pacholczyk, Rebecca Parker, Amyn Rojiani, **Ramses Sadek**, Allan Thornton, Nicholas Vahanian, Tobey MacDonald, and David H. Munn: Radio-immunotherapy using the IDO-inhibitor indoximod in combination with re-irradiation for children with progressive brain tumors in the phase 1 setting: an updated report of safety and tolerability (NCT02502708). The Society for Neuro-Oncology (SNO 2017)
- Asha Nayak-Kapoor, Zhonglin Hao, **Ramses Sadek**, Robin Dobbins, Lisa Marshall, Nicholas N. Vahanian, W. Jay Ramsey, Eugene Kennedy, Mario Mautino, Charles L. Link, Ray S. Lin, Stephanie Royer-Joo, Xiaorong Liang, Kari Morrissey, Sami Mahrus, Bruce McCall, Andrea Pirzkall, David H. Munn, John E. Janik, Samir N. Khleif: "Phase Ia Study of the Indoleamine 2,3-dioxygenase 1 (IDO1) Inhibitor Navoximod (GDC-0919) in Patients with Recurrent Advanced Solid Tumors" Clinical Cancer Research (CCR 2017)
- **Ramses Sadek**, Li Fang Zhang, Houssein Abdul Sater: Breast Cancer Molecular Subtypes Association with Clinical Outcomes and Race. (ASCO 2017)
- Houssein Abdul Sater, **Ramses Sadek**, Li fang Zhang, Aaron Gopal, Jean-Pierre Blaize, David Yashar, Reena Patel, Swetha Aribindi, Hiral Patel, Shou-Ching Tang; Validity of 1% hormonal positivity cutoff by American Society of Clinical Oncology/College of American Pathologists (ASCO/CAP) Guidelines at Georgia Cancer Center. (ASCO 2017).
- Pyrzak, A., Dow, J., **Sadek, R.**, & Rungruang, B.: Choosing Wisely: A cross-sectional survey of gynecologic oncologist practice patterns and concordance with current SGO recommendations. (Annual SGO winter meeting, 2017).
- Badi El Osta, Fengjiao Hu, **Ramses Sadek**, Rohini Chintalapally, Shou-Ching Tang. Immune checkpoint inhibitors (ICI): A meta-analysis of immune-related adverse events (irAE) from cancer clinical trials. (ASCO 2016).
- Garrick A, Pyrzak A, Hu F, **Sadek R**, Wheatley D, Rungruang BJ, Ghamande S: Impact of support group participation in women with gynecologic cancer. Palliative care in Oncology Symposium (2016).

- Andrea Garrick, Adam Pyrzak, Fengjiao Hu, **Ramses Sadek**, Donna Wheatley, Bunja Jane Rungruang, Sharad A. Ghamande: Impact of support group participation in women with gynecologic cancer. (ASCO 2016).
- Wilder C, Fridlyand D, Pace B, Gibson R, Hu F, **Sadek R**, Neunert: Monitoring hydroxyurea adherence: Use of a novel medication event monitoring system. 10th annual sickle Cell Disease Research and Education Symposium and 39th National Sickle Cell Disease Scientific meeting (2016).
- Howard Colman, Frank Mott, Alexander Spira, Theodore Johnson, Yousef Zakharia, Nicholas Vahanian, Charles Link, Eugene Kennedy, **Ramses Sadek**, David Munn, Olivier Rixe A Phase 1b/2 Study of the Combination of the IDO Pathway Inhibitor Indoximod and Temozolomide for Adult Patients With Temozolomide-Refractory Primary Malignant Brain Tumors: Safety Analysis and Preliminary Efficacy of the Phase 1b Component. (ASCO 2016).
- Theodores Johnson, Cole Giller, Ian Heger, Eugene Kennedy, Ravindra Kohle, Waleed Murad, Amym Rojioani, **Ramses Sadek**, Nicholas Vahnian, Tobey MacDonald, and David Munn. Phase I trial of Indoximod in combination with temozolomide-based therapy for children with progressive tumors. American Society for pediatric Hematology/Oncology (2016)
- Jing Zhao, Yingfeng Xia, Joseph Kaminski, Zhonglin Hao, Frank Mott, Jeff Campbell, **Ramses Sadek**, Feng-Meng Kong. Treatment-related death during concurrent Chemotherapy for locally advanced non-small cell lung cancer: A meta-analysis of randomized studies. PLOS ONE (2016):
- Pyrzak A, Hu F, Rungruang BJ, **Sadek R**, Macfee MS, Ghamande S: Efficacy of levonorgestrel intrauterine device (LIUD) and transvaginal ultrasound (TVUS) as treatment and surveillance of women with early endometrial cancer (EC) and complex atypical hyperplasia (CAH) who are poor surgical candidates. Society of Gynecologic Oncology Annual Meeting on Women's Cancer (2016).
- Pyrzak A, Hu F, Rungruang BJ, **Sadek R**, Macfee MS, Ghamande S Management of Early Endometrial cancer (EC) and Complex Atypical Hyperplasia (CAH) by levonorgestrel IUD (LIUD): A Cost and Risk Reduction Analysis. Society of Gynecologic Oncology 2016 Annual Meeting on Women's Cancer.
- Jeff Campbell, Jing Zhao, David Zaenger, Lonnetta Colton, Rabii Madi, Byron Dasher, Catherine Ferguson, Ronald Lewis, Arthur Smith, **Ramses Sadek**, Martha Terris, Feng-Ming Kong. ASCO (2015). No Significant Difference in Overall Survival between Caucasians and African Americans Patients with Prostate Cancer: An Analysis of 1338 Patients from a Single-Institution.
- Nayak-Kapoor, Asha; Hao, Zhonglin; **Sadek, Ramses**; Dobbins, R; Marshall, L: 18th ECCO - 40th ESMO European Cancer Congress (2015). Phase 1a study of the safety, pharmacokinetics, and pharmacodynamics of GDC-0919 in patients with recurrent/advanced solid tumors.
- Andrea Garrick, Adam Pyrzak, Jeff Campbell, Bunja Jane Rungruang, **Ramses F. Sadek**, Sharad A. Ghamande. Palliative Care in Oncology Symposium (2015). Prospective study to evaluate impact of support group participation in women with gynecological cancer.
- Yousef Zakaria, Theodore Johnson, **Ramses Sadek**, David Munn, O. Rixe. Society for Neuro-Oncology 20th Annual Scientific Meeting, 2015. A phase I-II study of the combination of indoximod and Temozolomide for adult patients with temozolomide-refractory primary malignant Brain Tumors.
- Jian-Yue Jin, Weili Wang, Nan Bi, Randall K Ten Haken, Matthew Schipper, **Ramese Sadek**, Hong Zhong, Theodore S Lawrence, Feng-Ming (Spring) Kong (ASTRO 2014). Blood biomarker dependent survival model for patients of non-small cell lung cancer treated with radiotherapy.
- Feng-Ming (Spring) Kong, Jeff Campbell, Paul Stanton, Matthew Stenmark, Jing Zhao, **Ramses Sadek**, David Munn, Samir Khleif, Theodore S Lawrence (ASTRO 2014). Immunomodulating cytokines may improve overall survival prediction after radiation therapy in patients with locally advanced non-small cell lung cancer.
- Yousef Zakharia, Theodore Johnson, Howard Colman, Nicholas Vahanian, Charles Link, Eugene Kennedy, **Ramses Sadek**, Feng-Ming Kong, John Vender, David Munn, Olivier Rixe A

(ASCO 2014). Phase I-II Study of the Combination of Indoximod and Temozolomide for Adult Patients with Temozolomide-Refractory Primary Malignant Brain Tumors.

- Jing Zhao, **Ramses Sadek**, Ahmad Al-basheer, Zhonglin Hao, Frank Mott, Feng-Ming (Spring) Kong. (ASCO 2014). Treatment related deaths after concurrent chemoradiotherapy in locally advanced non-small cell lung cancer: A meta-analysis of randomized studies.

PRESENTATIONS

- Invited speaker upcoming for second Adaptive Clinical Trials Symposium on March 18-19, 2019. Philadelphia, PA. Title of the talk: Adaptive Oncology Clinical trials, an Overview.
- Invited Speaker, Biopharmaceutical Applied Statistical Symposium, October 14-19 (2018). Savannah, GA. Title : Adaptive Clinical Trial design: real life Examples.
- PRIDE Minority Program: served as Faculty and taught the following classes (seminars)
 1. Basic Biostatistics for Clinical research; 2. Clinical Trials design and analysis (2018)
- Hematology/Oncology fellows' seminar series: Adaptive clinical Trials applications in Oncology
- Considerations for advanced clinical trials and analysis in Oncology. Invited presentation, Biopharmaceutical Applied Statistical Symposium (BASS –XXIV) Savannah, GA. October, 2017.
- Sample size estimation in clinical studies. PRIDE: Program to Increase Diversity among Individual Engaged in Health-Related Research. Augusta, GA (July 2017).
- New trends in Oncology Clinical trials. University of South Florida, Tampa, FL. (June 2017).
- Teaching Biostatistics for Clinician: 18 lectures for Residents and Hematology/Oncology Fellows (2015-2017).
- Considerations When Assessing Benefit-Risk During Interim Analyses in Oncology Studies: Invited Speaker at: Interim Analysis Symposium, Philadelphia, PA (March, 2017).
- Understanding Biostatistics in Clinical Research –Sample Size & Power Considerations in Clinical Research at: Advances Analytics for Clinical data meeting. San Francisco, CA (January 2017).
- Biostatistics for clinical research, Study design and power analysis a 2-day course for the PRIDE mentorship program. July 2016.
- Biostatistics for clinical research, a 4-hour course for the PRIDE mentorship program. July 2015.
- Use a survival model to correlate single-nucleotide polymorphisms of DNA repair genes with radiation dose response in patients with non-small cell lung cancer. Elsevier AudioSlides. 2015.
- No Significant Difference in Overall Survival between African American and Caucasian Patients with Prostate Cancer: An Analysis of 1338 patients from a Single Institution. ASTRO 2015.
- Phase I clinical trials methods: PRIDE: Program to Increase Diversity among Individual Engaged in Health-Related Research. July 2015.
- Clinical Study design: PRIDE: Program to Increase Diversity among Individual Engaged in Health-Related Research. June 2015.
- Overview of Phase I Cancer Clinical Trials Design. Cairo University, Cairo, Egypt 2013.
- Biostatistical Terminology and general concepts used in Oncology research. Oncology/Hematology fellows. GRU cancer Center. Augusta, GA. 2013
- TITE-CRM application to seamless Phase I/II non-small-cell Lung cancer trail, University of North Carolina, Chapel Hill. 2012
- TITE-CRM application to a Stereotactic Phase I/II non-small-cell Lung cancer trail, Georgia Health Science University Cancer Institute. Augusta, GA 2012
 - Issues in Design and Analysis of in Vitro Diagnostics Clinical Trials. BioMerieux Inc. 2010
 - Sample Size Consideration in Clinical Research: Medical Device Applications. bioMerieux Inc, Durham, North Carolina. 2009
 - Establishing Statistical Analysis Plan for Clinical Trials. bioMerieux Inc, Durham, North Carolina. 2009
 - Defining Success in Presence of Grey Areas/Uninterpretable Images. Invited Speaker, second annual statistical issues for Medical Devices. Washington, DC. 2009
 - Patient Reported Outcomes / Quality of Life Assessment in Clinical Research. Biopharmaceutical Applied Statistics symposium (BASS XV). Savannah, Georgia. 2008

- Validity and Reliability of Patient Reported Outcome Instruments. New England Research Institutes, Watertown, Massachusetts. 2008
- Analyzing Diagnostic Contrast Agent's Data: Some Pressing Issues. New England Research Institutes. Watertown, Massachusetts. 2008
- Use of Continuous Reassessment Method (CRM) in Seamless Phase I/II Small Cell Lung Cancer. American College of Radiology, Philadelphia, Pennsylvania. 2008
- On Designing Dose Limiting Toxicity Lung Cancer Trials. American College of Radiology, Philadelphia, Pennsylvania. 2007
- Design Consideration for Tenofovir Clinical Trials for HIV Prevention. Institute of Medicine, Washington, DC. 2007
- Case Studies for Outbreak Investigations: Ebola and Hantavirus. CDC, Atlanta, Georgia. 2007
- Sample Size And Power Consideration, Georgia Southern University, Statesboro, Georgia 2006
- Missing Data in Clinical Trials: An Overview. CDC, Atlanta, Georgia 2006
- Meta-Analysis of High-risk Sexual behavior in Persons Aware And Unaware They Are Infected With HIV in the United States. CDC, NCHSSTP/DHAP. Sadek, R., Marks, G. (2005)
- Characteristics of Immigrant Mothers with HIV. CDC/NCHSTP. 2005
- Handling Missing Data in HIV Research. Sadek, R., Gvetadze R, CDC Applied Statistical Symposium. Washington, DC.. 2004
- Efficacy of a Brief Case Management Intervention to Link Recently Diagnosed HIV-Infected Persons to Care. Sadek, R, Gardner L. Presented at Public Health and Environment meeting, Washington, DC. 2004
- Intention to Treat Analysis in Clinical Trial: An Overview: CDC/NCHSTP. 2004
- Moments for Order Statistics of the Generalized Gamma Distribution: A Computational Approach. Younan W., Selim K, Sadek R., Joint statistical meeting, San Francisco, California. 2003
- Morbidity and Mortality in the HERS. Gardner L., Sadek R. Epidemiology Branch Science meeting. 2003
- Sample Size And Power Calculations. CDC/NCHSTP. 2003
- VAERS System: Past, Present, and Future, Sadek R. and Iskander, CDC\National Immunization Program, Special Seminar. 2001
- Anthrax Safety And Efficacy: NIP Prospective. CDC\National Immunization Program Issues meeting. 2000
- Survival Analysis of Ebola Outbreaks, Eastern Virginia Medical School, Norfolk, Virginia. 1998
- Instructional Subgroups for the Adult Population with Learning Disabilities. Gregg, N, Sadek, R, & Curtis, R. American Educational Association Meeting. 1997
- Safety and Efficacy of Open Label Intravenous Ribavirin for Hantavirus Pulmonary Syndrome. Special Pathogens Branch, NCID, CDC. Sadek R, Chapman L, et al. 1996
- Using Monte Carlo Methods in Discriminant Analysis. Sadek R & Huberty C. Paper presented at the annual meeting of American Educational Research Association, New Orleans. 1994
- Evaluation of the Performance of Several Methods of Estimating the Shape Parameters of the Standard Beta Distribution. Sadek R, Selim Z. Proceedings of the 27th Annual Conference of Statistics, Computer Science, Operations Research and Mathematics. Institute of Statistical Studies & Research, Cairo University. 1993
- On Outlier Influence in Classification Analysis. Sadek R, Huberty C. Presented at the annual meeting of the American Educational Research Association, San Francisco. 1992
- On the Kernel Estimation of the Density Function of a Nonhomogeneous Poisson Process. Amara A, & Sadek R. Proceedings of the 18th Annual Conference of Statistics, Computer Science, Operations Research & Mathematics. Institute of Statistical Studies & Research, Cairo University. 1984

ACADEMIC AREAS OF INTEREST

- Oncology Research
- Clinical Trials Design And Analysis
- Interim analysis, and adaptive design
- Incomplete Data Analysis
- Laboratory Data Analysis
- Burden of Disease Analysis
- Epidemiology
- Biostatistics
- Survival Analysis
- HIV Research
- Discriminant Analysis
- Logistic Regression
- Experimental Design
- Longitudinal Studies

REPRESENTATIVE RESEARCH PROJECTS

Oncology Studies sample:

- Phase II Trial of the IDO Pathway Inhibitor Indoximod plus Pembrolizumab for the Treatment of Patients with Advanced Melanoma (2019)
- Phase I Study of the Non-receptor Kinase Inhibitor Bosutinib in Combination with Pemetrexed in Patients with Selected Metastatic Solid Tumors. (2019)
- Phase I feasibility and Safety study of nivolumab in combination with irinotecan in relapsed or refractory Small Cell Lung Cancer (SCLC) followed by maintenance nivolumab (2019)
- Phase 2 trial using indoximod-based chemo-radio immunotherapy for treatment of patients age 3 to 21 years who have progressive brain cancer (2019).
- "Improving effectiveness of immunotherapy by targeting the microenvironment in preclinical models of breast cancer" July-Aug 2019
- Autophagy agent (HCQ) in combination with carboplatin/gemcitabine followed by immunotherapy (2018)
- Dynamic regulation of CD73 expression in Cancer associated fibroblast enforces the immunosuppressive microenvironment.(2018)
- CCR renewal- Targeting dual inflammatory switch in tumors and prometastatic niche (2018)
- SOCS3: A critical link between inflammation and breast cancer metastasis (2018)
- Targeting the S100A8/S100A9 complex to overcome immune mediated metastasis (2018)
- Critical role of inflammatory cytokine network in breast cancer metastasis (2018)
- Immune regulation of tumor plasticity during metastatic process(2018)
- Linking mevalonate and mitochondrial metabolism in high-risk neuroblastoma (2018)
- Relevance to Human Health – Mevalonate and mitochondrial metabolism as a Therapeutic target for high-risk neuroblastoma.(2018)
- Understanding Mechanisms of Resistance to Anti-angiogenic Treatment(2018)
- Targeting primary tumor microenvironment and metastatic niche in breast cancer (2018)
- A novel Hsp90 Machine Inhibitor Combining Cancer Cell Toxicity and Immunotherapy. (2018)
- Statistical modeling for trend toward an inverse correlation between CD34 yield and viability (2018).
- A phase Ib /II trial of pembrolizumab and idelalisib in patients with non-small cell lung cancer (NSCLC) who have failed immune checkpoint inhibitor Georgia Cancer Center & Merck 2018.
- A phase I/II trial of pembrolizumab (MK-3475) and poly-ICLC in patients with metastatic mismatch repair-proficient (MRP) colon cancer. 2018.

- Dr. Ding: Data analysis for manuscript and study Higher SCAP expression or lower INSIG2 expression is associated with worse patient survival (\$560 was charged for the service) February 2019
- Participation in clinical trials may overcome health disparities in the survival of advanced or recurrent epithelial ovarian cancer. (July 2018)
- Disparities in Carcinosarcoma Cancer/ Survival analysis (Aug-sep 2018)
- Genetic in Early Ovarian Cancer(Aug-Sep 2018)
- The GT198 biomarker to address the taxane resistance. GRU Cancer Center and DoD (2015). Immune correlatives studies on tissues obtained from patients treated on phase I/II clinical trial of trastuzumab in combination with MEDI4736, an anti-PDL1 monoclonal antibody, for metastatic HER2 positive breast cancer who progressed on trastuzumab-containing regimen. Georgia Cancer Center with ASCO award.
- Phase II trial of indoximod and weekly taxol in platinum resistant ovarian cancer. Georgia Cancer Center and NewLink Genetic INC. (2015)
- Treatment of triple negative breast cancer with chemotherapy and indoximod. Georgia cancer Center and NewLink Genetics INC. (2015).
- Phase II trial of indoximod and weekly taxol in platinum resistant ovarian cancer. Georgia cancer Center and NewLink Genetics INC. (2015).
- Phase II randomized trial of indoximod and induction chemotherapy for the treatment of AML. Georgia cancer Center and NewLink Genetics INC. (2015).
- A phase I/II trial of MEDI4736 in combination with AZD5363 in patients with solid tumors and extension in advanced NSCLC. Georgia Cancer Center and MedImmune INC. (2015)
- A phase I/II trial of stereotactic body radiation therapy (SBRT), MEDI4736 and tremelimumab in patients with locally advanced and metastatic pancreatic cancer. Georgia Cancer Center and MedImmune INC. (2015)
- A Phase I/II Study of the combination of trastuzumab and MEDI4736 in adults with her2+ breast cancer. Georgia Cancer Center and MedImmune INC. (2015)
- A Phase I study of cyclophosphamide in combination with durvalumab and Tremelimumab. Georgia Cancer Center and MedImmune INC. (2015).
- A Phase II trial of selenium in combination with durvalumab and tremelimumab in renal cell Cancer. Georgia Cancer Center and MedImmune INC. (2015)
- A phase I trial of pembrolizumab and poly ICLC in patients with MSI high colon cancer. Georgia Cancer Center and Merck INC. (2015).
- A Phase II trial of Chemo radiation in combination with pembrolizumab in patients with locally advanced cervical cancer. Georgia Cancer Center and Merck INC. (2015).
- A Phase I/II trial of pembrolizumab and idelalisib in patients with NSCLC. Georgia Cancer Center and Merck INC. (2015).
- A phase I study of pembrolizumab in MSI cervical cancer. Georgia Cancer Center and Merck INC (2015).
- A phase I study of pembrolizumab and SBRT in ovarian cancer. Georgia Cancer Center and Merck INC. (2015).
- A phase I trial of ras peptide vaccine and pembrolizumab in colon, pancreatic and lung cancer. Georgia Cancer Center and Merck INC (2015).
- Window of opportunity study of idelalisib in patients with head and neck, colon, and bladder Cancer. Georgia Cancer Center and Gilead Science (2015).
- A retrospective study of GT198 expression and response to paclitaxel in breast cancer patients. Georgia Cancer Center (2015).
- A phase I/II trial of MEDI4736, an anti PD-L1 monoclonal antibody, in combination with AZD5363, a pan-AKT inhibitor in patients with refractory solid malignancies and in patients with recurrent or metastatic non-small cell lung cancer who have failed a first line platinum-based regimen. Georgia Cancer and AstraZenica (2015).
- A phase I/ Randomized Phase IIa trial of indoximod, 1-methyl-D-tryptophan in combination with idarubicin and cytarabine in patient with newly diagnosed acute myeloid leukemia. (2015)

- A phase I/II trial of concomitant administration of Indoximod plus ipilimumab for adult patients with metastatic melanoma.(2015)
- A Phase I/II study of the combination of Indoximod and Temozolomide for adult patients with Temozolomide-refractory primary malignant brain tumors. NewLink Genetic Corporation and Georgia Cancer Center.(2014)
- A phase I/II study of indoximod in combination with gemcitabine and non-paclitaxel in patients with metastatic adenocarcinoma of the pancreas. NewLink Genetic Corp. & Georgia Cancer Center (2014).
- Aspirin use and P13K mutation in Breast Cancer: A pilot study. Georgia Cancer Center. (2014)
- Phase I trial of Indoximod in combination with temozolomide-based Therapy for Children with progressive Primary brain Tumors. NewLink Genetic Corporation & Georgia Cancer Center.(2014)
- Phase I/II randomized trial of indoximod in combination with idarubicin and Cytarabine in patients with newly diagnosed Acute Myeloid Leukemia (AML). (2014)
- A Randomized Phase II Trial in Patients with Operable Stage I Non-Small Cell Lung Cancer: Radical Resection versus Stereotactic body radiotherapy. Georgia Cancer Center. (2013)
- A Phase I Trial of Vemurafenib in Combination with Erlotinib in Patients with BRAF V600 Mutant Metastatic or Unresectable Melanoma that Progressed on Vemurafenib Monotherapy. Georgia Cancer Center.(2013)
- A therapeutic trial for safety and preliminary efficacy of the combination of axitinib and selenomethionine (SLM) for adult patients with advanced clear cell renal cell carcinoma (CCRCC). Georgia Cancer Center. 2013
- A phase I/II study of nivolumab with combined modality therapy for unresectable stage IIIA/B non-small cell lung cancer. Georgia Cancer Center.
- A phase 1 study of NLG 919 for adult patients with recurrent advanced solid tumors. Georgia Cancer Center. 2013
- A Pilot Study to Test the Feasibility and Immunologic Impact of Sipuleucel-T (Provenge™) Administered with or without anti-PD-1 mAb (CT-011) and Low Dose Cyclophosphamide in Men with Advanced Castrate-resistant Prostate Cancer. Georgia Cancer Center. 2013
- A pilot study to test the feasibility of the combination of Gemcitabine and anti-PD1 monoclonal antibody (CT-011) in the treatment of resected pancreatic cancer. Georgia Cancer Center.
- A Phase I-2 Study of the combination of 1-Methyl-D-tryptophan (indoximod) and Ipilimumab for adult patients with metastatic melanoma. Georgia Cancer Center.2013
- Prospective trial of EGFR-targeted therapy for aggressive recurrent respiratory papillomatosis (RRP). 2013
- Phase 1-2 Study evaluating high dose (1×10^{10} CFU) ADXS11-001 treatment in women with HPV+ squamous cell carcinoma of the cervix. Georgia Cancer Center. 2013
- A Phase I open label dose-escalation study to investigate the safety, pharmacokinetics, pharmacodynamics and clinical activity of BXQ-350 in patients with advanced solid tumors and glioblastoma multiforme (GBM). Georgia Cancer Center. 2013
- A Randomized, Double Blind, Multicenter, Parallel-Group, Phase III Study to Evaluate Efficacy and Safety of DCVAC/PCa Versus Placebo in Men with Metastatic Castration Resistant Prostate Cancer Eligible for 1st Line Chemotherapy. 2013
- A Phase I, Multicenter Study of MRX34 Given Intravenously Two Times per Week for Three Weeks, Repeated Every Four Weeks in Patients with Unresectable Primary Liver Cancer or Advanced or Metastatic Cancer With Liver Involvement. 2013
- Confirmatory Study to Examine Negative Predictive Value (NPV) and Safety of Skin Testing with PRE-PEN, a Minor Determinant Mixture (MDM) of Penicillin Antigens, and Amoxicillin Reagent Against an Oral Challenge with Amoxicillin. 2013
- A Phase 1, Single-blind, Randomized, Two-way, Crossover Bioequivalence Study of Intravenously Administered ATI-0918 in Patients with Ovarian Cancer that has Progressed or Recurred after Platinum-based Chemotherapy. 2013
- An open label, multicenter, Phase II study to determine the safety and efficacy of BIND-014 (Docetaxel Nanoparticles for injectable suspension) administered by intravenous infusion to Patients with non-small-cell lung cancer. 2013

- Seamless Phase I/II Study of Stereotactic Lung Radiotherapy (SBRT) for Early Stage, Centrally Located, Non-Small Cell Lung Cancer (NSCLC) in Medically Inoperable Patients. 2013

Sickle Cell Disease (NIH-Funded Studies)

- Renoprotection with Losartan® in Macroalbuminuric patients with Sickle Cell Nephropathy. Funded by the National Institutes of Health National Heart, Lung, and Blood Institute. PI : Antonio Guasch, M.D. Emory University, Atlanta, Georgia. (2008-09)
- Losartan2: to assess whether Losartan® will reduce the rate of progression to overt nephropathy in microalbuminuric patients with sickle cell nephropathy. PI: Antonio Guasch, M.D. Emory University, Atlanta, Georgia. (2008-09)
- Preventing Acute Chest Syndrome by Transfusion (PROACTIVE) Feasibility Pilot Trial. Funded by the National Institutes of Health National Heart, Lung, and Blood Institute. PI: Lori Styles, Children's Hospital & Research, Oakland, California (2008-09)
- Improving Pain Rx and outcomes with various strategies of PCA. Funded by the National Institutes of Health National Heart, Lung, and Blood Institute. PI: Carlton Dampier, M.D. (Emory University), and Wally Smith, M.D. (2008-09)

HIV Research

- Phase II extended safety trial of Tenofovir Disoproxil Fumarate (TDF) among HIV negative men. Randomized, placebo-controlled, double-blinded, four-arm, multi-site trial (ARCA, SFDPH, Boston). CDC (2005-2009)
- Study of the Safety and Efficacy of Daily Tenofovir to Prevent HIV Infection Among Injection Drug Users in Bangkok, Thailand (Bangkok Tenofovir Study) n Phase II/III Randomized, placebo-controlled, double-blind trial Sponsors: CDC, Thailand Ministry of Health (2005-2008)
- Study of the safety and efficacy of daily oral antiretroviral use for the prevention of HIV infection in heterosexually active young adult in Botswana. Randomized, placebo-controlled, double-blinded, multi-site trial. CDC (2007-2010)
- Phase II/III Trial to Study the Safety and Efficacy of Truvada Intermittent Pre Exposure Prophylaxis (iPrEP) to Prevent HIV Infection among Men Who Have Sex with Men (MSM) in Bangkok, Thailand (The PrEP Study). Randomized, double-blind, two-arm, placebo-controlled study. Sponsors: CDC, Thailand Ministry of Health (2004-2008)
- A Phase I Study of the Safety and Acceptability of UC-781 Topical Vaginal Microbicide in Heterosexual Women and their Male Partners. Randomized, placebo-controlled, three-arm trial. Sponsors: Emory University, CDC. (2005-)
- Parallel Comparison of Tenofovir & Emtricitabine /Tenofovir Pre-Exposure prophylaxis to Prevent HIV-1 Acquisition within HIV-1 Discordant Couples. Phase III, multi-site, randomized, double-blinded, placebo-controlled, three-arm trial. Sponsors: University of Washington; funded by the Bill and Melinda Gates Foundation. (2003-2008).
- Phase I Study of the Safety and Acceptability of UC-781 Topical Vaginal Microbicide in Women and their Male Partners, Chiang Rai, Thailand randomized, placebo-controlled, three-arm trial. Sponsor: CDC
- The Longitudinal Epidemiologic Study to Gain Insight into HIV/AIDS in Children and Youth (LEGACY). CDC/HSTTP/DHAP
- Willingness to participate in HIV vaccine efficacy trials among three Black/African American communities in US. CDC, Atlanta
- Study to Understand the Natural History of HIV/AIDS in the Era of Effective Therapy (The "SUN" Study). CDC, Atlanta
- The HIV Outpatient Study (HOPS)
- A Prospective cohort study to estimate incidence of HIV seroconversion and to identify determinants of successful recruitment and retention among young adults in rural western Kenya
- Mother-Infant Rapid Intervention at Delivery (MIRIAD)

- Pediatric Spectrum of HIV Diseases Project (PSD)
- An Intervention to Promote Adherence to Antiretroviral Medications Among HIV-Infected Children 5-13 Years of Age.
- The Epidemiologic and Biologic Determinants of HIV Infection
- Determination of the spread and distribution of a potential rectal microbicide agent and semen surrogate.
- Phase II Extended Safety Study of Tenofovir Disoprox Fumarate (TDF) among HIV-1 Negative Men.
- A Pilot Protocol to Determine Effects of Chemical and Mechanical Stress on Rectal Permeability as a Surrogate for Toxicity in Evaluation of Rectally Applied Microbicides.
- Perinatal AIDS Collaborative Transmission Study -- HIV Follow up of Perinatally Exposed Children (PACTS-HOPE).
- Adolescent Impact: Behavioral intervention to improve health and reduce transmission risk of adolescents with HIV.
- Focus groups to inform a trial of daily Tenofovir to prevent HIV infection among injection drug users on Bangkok Thailand (Bangkok Tenofovir Study).
- Pathobiological of breast milk among HIV-1 infected Ugandan women receiving intrapartum Nevirapine.
- Rapid Assessment of Community Perceptions and Preferences on HIV Research Initiation in Rural Western Kenya.
- Participants of African American and Latinos in HIV Vaccine Trials.
- An Assessment of the Determinants of HIV Risk Factors for African American and Hispanic Women in the Southeastern United States.
- Examination of mucosal factors that may confer protection to HIV-1 exposed, Persistently seronegative women in Chiang Mai, northern Thailand.
- Factors affecting heterosexual transmission of HIV in Thailand.
- Immunogenetic testing of PBMC specimens from HIV-concordant and HIV-discordant couples for effects on HIV-1 clade E transmission.
- Survival of HIV-Infected Male Blood Donors and Their infected Partners in Northern Thailand.
- Survival among HIV-subtype E infected participants in the study of HIV transmission between Thai couples - role of hos...and viral factors in the disease progression.
- Characterization of sero-negative women with high level exposure to HIV-infected men compared to women found to be sero-positive after a short period of exposure.
- Parents Matter! Interventions to Promote Effective Parent-Child Communities about Sex and Sexual Risk Among African American Families.
- Study of the Safety and Efficacy of Daily Tenofovir Disoproxil Fumarate for the Prevention of HIV Infection in Heterosexual Active Young Adults in Botswana.
- Prevalence of Colonization and Incidence of Infection with Community-associated.
- Measuring the effect of injectable progesterin contraception use on the incidence on HIV Infection and Protective Behaviors.
- A Phase II open label clinical trial of maternal zidovudine/lamivudine and nevirapine for maximal reduction of mother-to-child HIV TRANSMISSION IN resource limited settings among breastfeeding populations in Kisumu Kenya (the Kisumu Infant Breastfeeding Study, KiBS).
- An Observational Study of Treatment Effectiveness and Resistance Patterns among Women Initiating Treatment with Non-nucleoside REVERSE TRANSCRIPTASE Inhibitor-based HAART after Previous Single Dose Nevirapine for Prophylaxis against Transmission of HIV.

Outbreak Investigations and Other Infectious Diseases

- Prevalence of Antibodies to Arenaviruses in rodents from the Southern and Western United States: CDC, Atlanta, 1995.

- Intravenous Ribavirin for Hantavirus Pulmonary Syndrome: safety during one year of Open Label Experience: CDC, Atlanta. 1996.
- An Outbreak of Crimean Hemorrhagic Fever in the United Arab Emirates, 1994-1995. PI: Ali Khan, M.D. CDC, Atlanta.
- Long-term safety follow-up of anthrax vaccinees, research on knowledge, attitudes and beliefs towards anthrax. DoD, and CDC, 2001
- Data mining for vaccine adverse event reporting system (VAERS). CDC, Atlanta, 2001
- Small-cell lung cancer ACR
- Ebola outbreak, Zaire 1995: CDC
- The Epidemiology of Rodent Bite and Rat Infestation in New York City. CDC, Atlanta, 1995-1996.
- Hanta virus outbreak in four-corner states 1994-1995. CDC
- Lassa Fever outbreak, Sierra Leon, 1995-1996, CDC
- Study of Learning disability, College of Education, University of Georgia, 1994-1995.
- Cost-analysis of different management polices for patients with mild hepatitis A virus infection in Kazakhstan. CDC-WHO 2005
- Neonatal mortality and site of hospital delivery by level of prenatal care among very low birth weight infants. CDC, and Georgia Dept. of Health (2001-2002)
- Density Estimates of rural dog populations and an assessment of marking methods during a rabies vaccination campaign in the Philippines. CDC 1995-1996
- The Egyptian National Hypertension Project (1993-1994). Funded by USAID, run by Cardiology Department, College of Medicine. Cairo University.

Anthrax Studies (CDC and DoD Collaborations)

- Anthrax Vaccine Adsorbed (AVA): Human Reactogenicity and Immunogenicity Trial to address change in Route of Administration and dose reduction. CDC and DoD. (2001).
- Assessment of Anthrax Knowledge, Attitudes, and Belief (KAB) and educational needs among military service and health care personnel in U.S. and Korea.
- Long term Follow-up of Anthrax Vaccine (compared to control group).
- Study of network and healthcare cents (VHC) to enhance the safety surveillance and quality assurance of the AVA immunization program within DoD.
- Anthrax meta-analysis to assess safety and efficacy of the Anthrax Vaccine Adsorbent using 16 studies.
- Aberration detection and data mining to assess the association between groups of adverse events and AVA.

Diagnostics Research (mostly industry)

- A prospective evaluation to demonstrate the equivalency of the VIDAS NEW instrument to VIDACE instrument using clinical samples and biological assays. (2011)
- Evaluating the performance characteristics of the bioMerieux Troponin I assay for U.S., CE and global markets. (2011)
- A prospective multi-center matched design study evaluating the performance characteristics of VIDAS free Thyroxine (FT4) assay. (2011)
- Clinical Evaluation of bioMerieux companion diagnostic assay for detection of B-raf mutations associated with treatment of melanoma with GSK drug for Phase III (MEKi). 2011
- Clinical Evaluation of bioMerieux companion diagnostic assay for detection of B-raf mutations associated with treatment of melanoma with GSK drug for Phase II (MEKi). 2011
- Clinical Evaluation of bioMerieux companion diagnostic assay for detection of B-raf mutations associated with treatment of melanoma with GSK drug for Phase III (BRAFi). 2011

- Clinical Evaluation of bioMerieux companion diagnostic assay for detection of B-raf mutations associated with treatment of melanoma with GSK drug for Phase II (BRAFi). 2011
- Clinical Evaluation of bioMerieux companion diagnostic assay for detection of B-raf mutations associated with treatment of melanoma with GSK drug for Phase III drug combination of BRAFi and MEKi.2011
- Phase III Clinical trial to study safety and efficacy of Samerim® on patients with Rheumatoid arthritis., Mallinckrodt Inc. Saint Louis, Missouri (1997-99)
- Phase III Clinical trial to study safety and efficacy of AngioMark® as a diagnostics media for Rheumatoid arthritis, Mallinckrodt Inc. Saint Louis, Missouri (1997-99).
- Bioequivalence study for Methylphenidate (Retlin®). Mallinckrodt Inc. Saint Louis, Missouri (1998-99).
- Bioequivalence study for Flauxtine (Prozak®). Mallinckrodt Inc. Saint Louis, Missouri (1998-99)
- A Prospective, Multi-center, Double-blinded, Placebo-Controlled, Randomized Trial Utilizing the VIDAS® B.R.A.H.M.S. Procalcitonin Test to Identify which COPD Subjects Experiencing a Mild to Moderate Exacerbation Would Not Benefit from Antibiotic Therapy. bioMerieux Inc. (2009)
- VIDAS Lyme IgM is an in-vitro diagnostic assay for the qualitative detection of specific IgM against *Borrelia burgdorferi sensu lato* in human serum or plasma, as an aid in the diagnosis of Lyme disease. bioMerieux Inc. (2009)
- VIDAS D-Dimer Exclusion II Cut-Off Verification and Specimen Stability Study and clinical trial. bioMerieux Inc. (2009)
- VIDAS® TOXO avidity assay evaluation for use on VIDAS instruments for the determination of antitoxoplasma IgG avidity in human serum using the ELFA technique (Enzyme Linked Florescent Assay). bioMerieux Inc. (2009)
- A multi-center clinical trial to assess clinical performance of the NucliSENS EasyQ® MRSA test in comparison with reference culture method. bioMerieux Inc. (2010).
- Clinical trial to compare VIDAS new scanner head to the current VIDAS instruments.
- Multi-center study to demonstrate that the Simon+ detection system in use with BacT/ALERT culture bottles is substantially equivalent to the BacT/ALERT 3d system in the detection and recovery of microorganism from blood and from (Sterile body fluid, SBF) taken from patients suspected of having bacteremia/fungimia (SBF infection. bioMerieux Inc. (2009)
- 20. Evaluation of VIDAS Anti-TG as In Vitro diagnostic medical device for use with the VIDA 2 system for the determination of human anti thyroglobulin antibodies (Anti-Tg) in human serum or plasma. bioMerieux Inc. (2010)
- 21. Evaluation of VIDAS Anti-TPO as In Vitro diagnostic medical device for use with the VIDA system for the determination of human anti thyroid peroxides antibodies (Anti-TPO) in human serum or plasma. bioMerieux Inc. (2010)
- A prospective, multi-center Clinical trial to evaluate the performance characteristics of the chromID C.difficile on human biological specimen. bioMerieux Inc. (2010).
- Study to evaluate the performance of TSPOT-TB® for diagnosis of latent TB. Oxford Immunotech, Oxford, England (2006).

CONTINUING EDUCATION AND TRAINING

Training logs and certificates are available upon request

Doctoral dissertations Committees:

- **Aly El-Hefnawy El-Dessouky, Cairo University:** Mathematical programming approach to Discriminant Analysis with application in Demography. Cairo University, Faculty of Economics and political Sciences, Department of Statistics. PhD awarded in 1999.

- 2 **Anthony Satella: Tulane University:** Factors associated with Hospitals length of stay, mortality, and total charges among HIV-infected adults: An analysis of the Louisiana hospital inpatient discharge database. A dissertation submitted to the department of health systems management in a partial fulfillment of the requirements of the School of Public Health and Tropical Medicine of Tulane University for the degree of Doctor of Public Health. 2007