Essam Ahmed Ghazaly Kerwash

Title of the talk: Regulatory perspective on the use and qualification of PBPK modelling.

Bio sketch:

- **Name:** Dr Essam Ahmed Ghazaly Kerwash, MB BCh, MSc, PhD, MD, FHEA
- **Position**: Accredited Pharmacokinetics Assessor, MHRA, UK.
- **Background**: Dr Essam Kerwash has two year of experience in regulatory and works on the assessment of the pharmacokinetic aspects of new drug applications. Prior to joining the MHRA in January 2017, Essam worked for several years in academia where he taught clinical pharmacokinetics to medical students and studied the clinical pharmacokinetics during drug development. Essam has experience in population and physiologically based modelling (PBPK) and authored number of publications on PBPK modelling and pharmacokinetics during early phase drug development of new anti-cancer agents.
- Role in PEARRL: Dr Essam designed the pharmacokinetics teaching curriculum for PEARRL students during their secondment in the MHRA and supervised the MHRA research projects for two of the ESRs.

Recent publications :

1. Blagden SP, Rizzuto I, Suppiah P, O'Shea D, Patel M, Spiers L, Sukumaran A, Bharwani N, Rockall A, Gabra H, El-Bahrawy M, Wasan H, Leonard R, Habib N, Ghazaly E (2018). Anti-tumour activity of a first-in-class agent NUC-1031 in patients with advanced cancer: results of a phase I study. Br J Cancer;119(7):815-822.
2. van Eijkelenburg NKA, Rasche M, Ghazaly E, Dworzak MN, Klingebiel T, Rossig C, Leverger G, Stary J, De Bont ESJM, Chitu DA, Bertrand Y, Brethon B, Strahm B, van der Sluis IM, Kaspers GJL, Reinhardt D, Zwaan CM (2018). Clofarabine, high-dose cytarabine and liposomal daunorubicin in pediatric
3. relapsed/refractory acute myeloid leukemia: a phase IB study. Haematologica103(9):1484-1492.
4. Bilanges B, Alliouachene S, Pearce W, Morelli D, Szabadkai G, Chung YL, Chicanne G, Valet C, Hill JM, Voshol PJ, Collinson L, Peddie C, Ali K, Ghazaly E, Rajeeve V, Trichas G, Srinivas S, Chaussade C, Salamon RS, Backer JM, Scudamore CL, Whitehead MA, Keaney EP, Murphy LO, Semple RK, Payrastre B, Tooze SA and Vanhaesebroeck B (2017). “Vps34 PI 3-kinase inactivation enhances insulin sensitivity through reprogramming of mitochondrial metabolism”. Nat Commun; 8(1):1804. doi: 10.1038/s41467-017-01969-4.
5. Manolis E, Brogren J, Cole S, Hay JL, Nordmark A, Karlsson KE, Lentz F, Benda N, Wangorsch G, Pons G, Zhao W, Gigante V, Serone F, Standing JF, Dokoumetzidis A, Vakkilainen J, van den Heuvel M, Mangas Sanjuan V, Taminiau J, Kerwash E, Khan D, Musuamba FT, Skottheim Rusten I; EMA
6. Modelling and Simulation Working Group (2017). “Commentary on the MID3 good practices paper”. CPT Pharmacometrics Syst Pharmacol; 6 (7):416-417. doi: 10.1002/psp4.12223.
7. Rizzuto I, Ghazaly E, Peters, Godefridus J (2017). “Pharmacological factors affecting accumulation of gemcitabine’s active metabolite, gemcitabine triphosphate”. Pharmacogenomics; doi: 10.2217/pgs-2017-0034.