

PERSONAL INFORMATION **Ragnhildur Heidarsdottir**

WORK EXPERIENCE

- August 2004-October 2006 **Researcher in Drug Development**
Decode Genetics (Iceland)
Method development, data processing and clinical animal drug researches.
- January 2010-August 2018 **Project Manager and expert in regulatory**
Teva/Actavis (Iceland)
Project Management and expert in drug product regulatory of marketing authorisation and variation applications. Writing SoPs and other in-house guidelines relevant to this area.
- September 2018- Present **Project Manager and expert**
Icelandic Medicines Agency (Iceland)
Evaluating and managing RMS slot requests, managing RMS and Rapp/Co-Rapp CP MAAs where Iceland is in the leading assessment role along with other MAAs. Also provide regulatory support and guidance to applicants of MAA along with performing the validation and coordination of the MAAs through out the application phases. Coordination of Scientific Advices. Writing SoPs.

EDUCATION AND TRAINING

- August 2001-May 2004 **Bachelor of Science (B.Sc.)**
University of Iceland (Iceland)
Biology: Molecular biology, cell biology, microbiology
- August 2007-January 2010 **Master of Science (M.Sc.)**
University of Iceland (Iceland)
MSc in Biomedical science with First Class with distinction: 9.43
- Master Thesis: n-3 Polyunsaturated Fatty Acids and the Risk of Postop Atrial Fibrillation.
1. Knowledge and understanding of the selected subject area
2. Practical ability and skills
3. Theoretical skills
4. Communication skills and information literacy
5. Learning skills
- August 2015-December 2015 **Project Management associate IPMA Level D**
International Project Management Association (Iceland)
Achieving IPMA level D certification is international recognition of your knowledge about managing projects. You have shown to know the competences as described by the IPMA International Competence Baseline®, and have shown to know how to apply them.. An IPMA Level D certification requires that the candidate has knowledge in the Competence Elements (CEs) related to project management. As such, they usually have broad project management knowledge and may work in a project team.
- Present **Training several**
EMA network learning center ()
Several trainings, webinars and presentation via EMA learning center in the regulatory area and other related areas.
- Present **Personal skills - courses**
Several in Iceland (Iceland)
Many courses on personal skills as a project manager. Time management, positive psychology in the project management.
- Present **Lean Management**
Several in Iceland (Iceland)
Many short or longer courses on this area.

ADDITIONAL INFORMATION

- Expertise**
- Project Management
 - Drug product regulatory
 - RMS slot request evaluation and coordination of decision making
 - MAA validation,overview assessment report preparation, similarity check, ASMF AR Worksharing procedure,
 - CP, DC, MR, zero day regulatory procedures managing
 - CTS
 - Scientific Advice (SA) coordination and preparation of documents etc from IRIS of EMA SAs
 - SoPs writing
 - Lean Management
 - Teams - Planner: Well competence
- Publications**
- Published :
- Metcalf RG, Skuladottir GV, Indridason OS, Sullivan TR, Bjorgvinsdottir L, Sanders P, Arnar DO, Gibson RA, Heidarsdottir R, Cleland LG, Palsson R, Farquharson AL, Young GD, James MJ. U-shaped relationship between tissue docosaehexaenoic acid and atrial fibrillation following cardiac surgery. *Eur J Clin Nutr*, 2014;68(1):114-118.
- Bjorgvinsdottir L, Indridason OS, Heidarsdottir R, Skogstrand K, Arnar DO, Torfason B, Hougaard DM, Palsson R, Skuladottir GV. Inflammatory response following heart surgery and association with n-3 and n-6 long-chain polyunsaturated fatty acids in plasma and red blood cell membrane lipids. *Prostaglandins Leukot Essent Fatty Acids*, 2013;89(4):189-94.
- Bjorgvinsdottir L, Arnar DO, Indridason OS, Heidarsdottir R, Skogstrand K, Torfason B, Hougaard DM, Palsson R, Skuladottir GV. Do High Levels of n-3 Polyunsaturated Fatty Acids in Cell Membranes Increase the Risk of Postoperative Atrial Fibrillation? *Cardiology*, 2013;126(2):107-114.
- Skuladottir GV, Heidarsdottir R, Arnar DO, Torfason B, Edvardsson V, Gottskalksson G, Palsson R, Indridason OS. Plasma n-3 and n-6 fatty acids and the incidence of atrial fibrillation following coronary artery bypass graft surgery. *Eur J Clin Invest*, 2011;41(9):995-1003.
- Heidarsdottir R, Arnar DO, Skuladottir GV, Torfason B, Edvardsson V, Gottskalksson G, Palsson R, Indridason OS. Does treatment with n-3 polyunsaturated fatty acids prevent atrial fibrillation after open heart surgery? *Europace*, 2010;12:356-363.
- Public lectures on Scientific Conferences:
- Lara Bjorgvinsdottir, Olafur Skuli Indridason, Ragnhildur Heidarsdottir, David O. Arnar, Bjarni Torfason, Runolfur Palsson, Kristin Skogstrand, David M. Hougaard, Gudrun V. Skuladottir. Omega-3 fjolomettadar fitusyrur, bolguthaettir og ahaetta a gattatifi eftir hjartaskurdadgerd. XV. Radstefna um rannsoknir i lif- og heilbrigdisvisindum i Haskola Islands. 5. - 6. januar 2011.
- Ragnhildur Heidarsdottir, Olafur S. Indridason, David O. Arnar, Bjarni Torfason, Runolfur Palsson, Vidar Edvardsson, Gizur Gottskalksson, Gudrun V. Skuladottir. Is there an association between n-3 polyunsaturated fatty acids and the incidence of postoperative atrial fibrillation? *Europace* 2009, The Meeting of the European Heart Rhythm Association, 24. juni 2009, Berlin.
- Ragnhildur Heidarsdottir, Olafur S. Indridason, David O. Arnar, Bjarni Torfason, Runolfur Palsson, Vidar Edvardsson, Gizur Gottskalksson, Gudrun V. Skuladottir. Do marine n-3 polyunsaturated fatty acids reduce the occurrence of postoperative atrial fibrillation? XXII Nordic-Baltic Congress of Cardiology, 3-5 June 2009 Reykjavik.
- Ragnhildur Heidarsdottir, Olafur Skuli Indridason, David O. Arnar, Bjarni Torfason, Runolfur Palsson, Vidar Orn Edvardsson, Gizur Gottskalksson, Gudrun V. Skuladottir. Styrkur omega-3 fjolomettadra fitusyra i blodi og tidni gattatifs eftir opna hjartaskurdadgerd. *Lyflaeknathing*, 6.-8. juni 2008, Selfossi.
- Ragnhildur Heidarsdottir, Olafur Skuli Indridason, David O. Arnar, Bjarni Torfason, Runolfur Palsson, Vidar Orn Edvardsson, Gizur Gottskalksson, Gudrun V. Skuladottir. Styrkur omega-3 fjolomettadra fitusyra i blodi og tidni gattatifs eftir opna hjartaskurdadgerd. *Lyflaeknathing*, 6.-8. juni 2008, Selfossi

Seminars:

Ragnhildur Heidarsdottir, Gudrun V. Skuladottir, Olafur Skuli Indridason, David O. Arnar. Styrkur omega-3 fitusyra i blodi og tidni gattatifs eftir opna hjartaskurdadgerd. Malstofa Laeknadeildir 7 mai 2009.

Ragnhildur Heidarsdottir, Olafur Skuli Indridason, David O. Arnar, Gudrun V. Skuladottir. Are plasma levels of n-3 PUFA associated with a lower incidence of postoperative atrial fibrillation? Lifvisindasetur HI 22. januar 2009.

Posters on scientific conferences:

Skuladottir Gudrun Valgerdur, Bjorgvinsdottir L, Heidarsdottir R, Arnar DO, Palsson R, Metcalf R, James M, Gibson R, Sanders P, Farquharson A, Young G, Indridason OS. Postoperative atrial fibrillation in relation to DHA and AA levels in plasma phospholipids and red blood cell membranes. 10. Congress of the International Society for the Study of Fatty Acids and Lipids (ISSFAL). Vancouver, Canada. 26.-30. mai 2012.

Skuladottir Gudrun Valgerdur, Bjorgvinsdottir L, Heidarsdottir R, Palsson R, Skogstrand K, Hougaard DM, Arnar DO, Indridason OS. Relationship of inflammatory mediators to n-6 and n-3 long-chain polyunsaturated fatty acids in plasma phospholipids and red cell membrane lipids following open heart surgery. 10. Congress of the International Society for the Study of Fatty Acids and Lipids (ISSFAL). Vancouver, Canada. 26.-30. mai 2012.

David O. Arnar, Lara Bjorgvinsdottir, Olafur Skuli Indridason, Ragnhildur Heidarsdottir, Bjarni Torfason, Runolfur Palsson, Gudrun V. Skuladottir. Eykur hatt hlutfall omega-3 fjolomettadra fitusyra i frumuhimnum haettu a gattatifi eftir opna hjartaskurdadgerd? XX.thing Felag islenskra lyflaekna. Harpa, Reykjavik. 16.-17. november 2012.

Lara Bjorgvinsdottir, Olafur Skuli Indridason, Ragnhildur Heidarsdottir, David O. Arnar, Bjarni Torfason, Runolfur Palsson, Kristin Skogstrand, David M. Hougaard, Gudrun V. Skuladottir. Omega-3 fjolomettadar fitusyrur, bolguthaettir og ahaetta a gattatifi eftir hjartaskurdadgerd. Fimmtanda radstefnan um rannsoknir i lif- og heilbrigdisvisindum i Haskola Islands. Haskolatorgi 5. og 6. januar 2011. Laeknabladid 97, Fylgirit 66, bls. 82, 2011.

David O. Arnar, Gudrun V. Skuladottir, Ragnhildur Heidarsdottir, Bjarni Torfason, Runolfur Palsson, Vidar Orn Edvardsson, Gizur Gottskalksson, Olafur Skuli Indridason. Draga reykingar ur ahaettu a gattatifi a fyrstu dogum eftir kransaedahjaveituadgerd? Fimmtanda radstefnan um rannsoknir i lif- og heilbrigdisvisindum i Haskola Islands. Haskolatorgi 5. og 6. januar 2011. Laeknabladid 97, Fylgirit 66, bls. 124, 2011.

Gudrun V. Skuladottir, Ragnhildur Heidarsdottir, David O. Arnar, Bjarni Torfason, Runolfur Palsson, Vidar O. Edvardsson, Gizur Gottskalksson, Olafur Skuli Indridason. Tidni gattatifs eftir kransaedahjaveituadgerd med tilliti til hlutfalls omega-3 og omega-6 fjolomettadra fitusyra i fosfolipidum blodvokva. Fimrtanda radstefnan um rannsoknir i lif- og heilbrigdisvisindum i Haskola Islands. Haskolatorgi 5. og 6. januar 2011. Laeknabladid 97, Fylgirit 66, bls. 124, 2011.

David O. Arnar, Gudrun V. Skuladottir, Ragnhildur Heidarsdottir, Bjarni Torfason, Runolfur Palsson, Vidar Orn Edvardsson, Gizur Gottskalksson, Olafur Skuli Indridason. Draga reykingar ur ahaettu a gattatifi a fyrstu dogum eftir kransaedahjaveituadgerd? XIX. THing Felags islenskra lyflaekna, Reykjavik 1.-2. oktober 2010. Laeknabladid 96, Fylgirit 65, bls. 14, 2010.

Lara Bjorgvinsdottir, Olafur Skuli Indridason, Ragnhildur Heidarsdottir, David O. Arnar, Bjarni Torfason, Runolfur Palsson, Kristin Skogstrand, David M. Hougaard, Vidar Orn Edvardsson, Gizur Gottskalksson, Gudrun V. Skuladottir. Tengsl omega-3 fjolomettadra fitusyra i himnum raudra blodkorna og bolguthatta i blodi hja sjuklingum sem gangast undir opna hjartaskurdadgerd. XIX. THing Felags islenskra lyflaekna, Reykjavik 1.-2. oktober 2010. Laeknabladid 96, Fylgirit 65, bls. 16, 2010.

Gudrun V. Skuladottir, Ragnhildur Heidarsdottir, David O. Arnar, Bjarni Torfason, Runolfur Palsson, Vidar O. Edvardsson, Gizur Gottskalksson, Olafur Skuli Indridason. Tidni gattatifs eftir kransaedahjaveituadgerd med tilliti til hlutfalls omega-3 og omega-6 fjolomettadra fitusyra i fosfolipidum blodvokva XIX. THing Felags islenskra lyflaekna, Reykjavik 1.-2. oktober 2010. Laeknabladid 96, Fylgirit 65, bls. 17, 2010.

Arnar DO, Skuladottir GV, Heidarsdottir R, Torfason B, Palsson R, Edvardsson VO, Gottskalksson G, Indridason OS. Smoking is associated with lower risk of postoperative atrial fibrillation. European Heart Journal. Journal of the European Society of Cardiology 31, Abstract Supplement, p 110, September 2010, Stockholm.

Skuladottir GV, Heidarsdottir R, Arnar DO, Torfason B, Palsson R, Edvardsson VO, Gottskalksson G, Indridason OS. Do high levels of n-3 PUFA in plasma phospholipids increase the risk of postoperative atrial fibrillation? 9th Meeting of the ISSFAL, p 191, May 29 - June 2, 2010,

Maastricht, The Netherlands.

Bjorgvinsdottir L, Indridason OS, Heidarsdottir R, Arnar DO, Torfason B, Palsson R, Skogstrand K, Hougaard DM, Edvardsson VO, Gottskalksson G, Skuladottir GV. Inverse relationship between n-3 PUFA in red blood cell membranes and inflammatory biomarkers in patients undergoing open heart surgery. 9th Meeting of the ISSFAL, p 191, May 29 - June 2, 2010, Maastricht, The Netherlands.

Ragnhildur Heidarsdottir, Olafur S. Indridason, David O. Arnar, Bjarni Torfason, Runolfur Palsson, Vidar Edvardsson, Gizur Gottskalksson, Gudrun V. Skuladottir. An increase in levels of interleukin-6 after cardiac surgery may contribute to the development of postoperative atrial fibrillation. XXII Nordic-Baltic Congress of Cardiology, 3-5 June 2009 Reykjavik.

Ragnhildur Heidarsdottir, Olafur Skuli Indridason, David O. Arnar, Bjarni Torfason, Runolfur Palsson, Vidar Orn Edvardsson, Gizur Gottskalksson, Gudrun V. Skuladottir. Tengist gattatif eftir opnar hjartaskurdadgerdir styrk omega-3 fjolomettadra fitusyra i blodi? Fjortanda radstefnan um rannsoknir i lif- og heilbrigdisvisindum i Haskola Islands. Haskolatorgi HI 5. og 6. januar 2009.

Heidarsdottir R, Indridason OS, Arnar DO, Torfason B, Palsson R, Edvardsson VE, Gottskalksson G, Skuladottir GV. Plasma levels of n-3 long-chain polyunsaturated fatty acids and incidence of atrial fibrillation following open heart surgery. 8th Meeting of the ISSFAL, 17-22 May, 2008, Kansas City, Missouri, USA.

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