

# **WP8: Project Management**

Bridget Glaysher



<b>ID</b>	<b>Title</b>	<b>Lead beneficiary</b>	<b>Due date</b>	<b>Date submitted</b>
D8.1	Project Management Handbook and calendar	UNIVDUN	Oct-13	13-Nov-13
D1.1	Copies of all required ethical approvals from national/legal authorities	UNIVDUN	Nov-13	04-Dec-13
D7.1	Establishment and launch of project website	UNIVDUN	Nov-13	04-Dec-13
D1.2	Agreed and published criteria for statin-induced myopathy	UOL	Feb-14	07-Mar-14
D2.1	Agreed and published criteria for ACEi/ARB-induced angioedema	UPP	Feb-14	07-Mar-14
D7.2	Progress newsletter 1	UNIVDUN	Aug-14	19-Sep-14
D1.3	Identification and recruitment of patients with statin-induced myopathy for the discovery sequencing	UOL	Feb-15	01-May-15



# Deliverables currently due

ID	Title	Lead beneficiary	Due date	Current status
D3.1	Exome sequencing results from discovery samples	UNIVDUN	Feb-15	Expected Oct 15?
D1.4	Identification and recruitment of patients for the internal replication phase	UOL	Aug-15	??
D2.2	Angioedema phenotype database	UPP	Aug-15	Expected Sep 15?
D3.2	Cross cohort sequence calling and QC report	UNIVDUN	Aug-15	Expected Oct 15?
D7.3	Progress newsletter 2	UNIVDUN	Aug-15	Expected Sep 15



# Remaining deliverables Dec 15 + April 16

ID	Title	Lead beneficiary	Due date	Any comments?
D3.3	Burden test analysis results	UNIVDUN	Dec-15	
D7.4	Optimised genetic test design	ASPER	Dec-15	
D4.1	Refined optimal marker set (SIM)	PGXIS	Apr-16	
D4.2	Refined optimal marker set (ACEi/ARB)	PGXIS	Apr-16	
D5.1	Replication results for statin myopathy	UU	Apr-16	
D5.2	Results of replication study for ACEi/ARB angioedema	UU	Apr-16	
D7.5	Pre-clinical test validation	ASPER	Apr-16	



# Remaining deliverables August 16

ID	Title	Lead beneficiary	Due date	Any comments?
D5.3	Population based validation of diagnostics	UU	Aug-16	
D5.4	Economic assessment report	UU	Aug-16	
D6.1	Results of siRNA screen for statin myopathy loci	UNIVDUN	Aug-16	
D6.2	Results of siRNA screen for ACEi/ARB angioedema loci	UNIVDUN	Aug-16	
D6.3	Joint model of SNP loci and expression networks	UNIVDUN	Aug-16	
D7.6	Public release of commercial diagnostic	ASPER	Aug-16	
D7.7	Pilot implementation	ASPER	Aug-16	
D7.8	Report on maintenance of website	UNIVDUN	Aug-16	





# THE PREDICTOR

PREDICTION-ADR

Newsletter 1

September 2014

## Utrecht hosts 2014 Plenary



The PREDICTION-ADR team

The first annual plenary meeting of the PREDICTION-ADR consortium was held at the historic Academiegebouw (University halls) in Utrecht on September 9th and 10<sup>th</sup>, 2014.

On the first day the progress and planning of recruiting cases and controls for the angioedema and myopathy was discussed.

Day two saw Colin Palmer of the University of Dundee update the team about the progress with sequencing harmonisation discussions and the reported and agreed protocol for the uniform

targeting of exome sequencing to be used for the main study.

All centres will use Illumina HiSEQ technology for the sequencing and third party providers for the exome capture reagents were agreed.

The use of control individuals who could be characterised as tolerant of both ACE inhibitors and statins was described to increase the power of the discovery phase of the study.

continued ...

Welcome to the Newsletter of PREDICTION-ADR

Personalisation of treatment in cardiovascular disease through next generation sequencing in Adverse Drug Reactions (PREDICTION-ADR)

Prediction-ADR aims to discover the genetic factors predisposing patients to adverse drug reactions (ADRs) from cardiovascular disease (CVD) drugs. This will be achieved by assembling a consented blood bank and DNA for a population of ~500 cases of ACEi induced angioedema and statin induced myopathy defined using a standardised phenotypic criteria.

PREDICTION-ADR has six partners in four countries:

- University of Dundee, UK
- Universiteit Utrecht, the Netherlands
- University of Liverpool, UK
- Uppsala Universitet, Sweden
- Pharmacogenomic Innovative Solutions Limited, UK
- Asper Biotech AS, Estonia

<http://www.prediction-adr.eu>  
Start date: 01 September 2013  
End date: 31 August 2016

## More from Utrecht ...

Alun McCarthy of Pharmacogenomic Innovative Solutions Ltd (PGIS) described the latest implementations of Taxonomy 3 software including the use of PREDICTION-ADR funding to optimise the software for parallel processing resulting in a substantial acceleration of the analytical pipeline that would benefit the exome sequencing project in PREDICTION-ADR.

The use of Taxonomy 3 to detect and remove ancestry outliers highlighted the need to carefully match the recruitment of both cases and controls at all the study centres. The novel use of Taxonomy 3 for drug target discovery in Rheumatoid arthritis funded by the Technology Strategy Board was described.

Anu Aaspõllu discussed the experience of SME partner

## PGIS to aid drug discovery in Rheumatoid Arthritis

PGIS has been awarded a Feasibility grant in the latest BioMedical Catalyst funding round from the UK Technology Strategy Board.

This grant will fund PGIS to apply its Taxonomy3 methodology to a rheumatoid arthritis genetic dataset, and to analyse the output to generate a short-list of novel drug targets. This will in turn support the PGIS objective to obtain external investment to establish

ASPER Biotech in implementing genetic tests in the marketplace and presented the regulatory accreditation that had been performed by this SME.

The CLIA accreditation was highlighted. Market research regarding the acceptability and desirability of genetic tests to predict adverse drug events was presented and discussed by the consortium.



Dom Tower of Utrecht

drug discovery programmes in-house.

PGIS plan to use our Taxonomy3 technology to identify novel drug targets, and to generate molecules acting via these targets. As these drug targets are based on human DNA data, the molecules acting through these drug targets will have a higher probability of success in clinical development.

## International experts agree on phenotype definitions

A joint workshop on phenotype definitions for statin associated myopathy and ACE inhibitor induced angioedema was held in Liverpool on the 10th December 2013. As well as the PREDICTION-ADR team, international experts in statin toxicity and angioedema from around Europe were in attendance for lively discussions on clinical and biochemical parameters to be considered in researching the genetics of adverse drug events.

Conclusions from this workshop were used to guide the publication of phenotype definition guidelines. Both of which have been published in *Clinical Pharmacology and Therapeutics*.

...

## ADR-research goes national in UK

Researchers in Liverpool, led by PREDICTION-ADR investigator Ana Alfirevic have announced that the MOLGEN network is now poised to be able to recruit myopathy and angioedema cases in 64 sites throughout the UK.

This uses a protocol common to all adverse drug reactions and is designed to capture all phenotypic information agreed at the Liverpool workshops. This highlights the efficiency of coordinating research across the entire UK National Health Service.



This project has received funding from the European Union's Seventh Framework Programme for research, technological development and demonstration under grant agreement no 602108



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Any suggestions for pieces to include in Newsletter 2 (D7.3)?

- 1<sup>st</sup> Periodic report went smoothly – thank you 😊
- 2<sup>nd</sup> reporting period (and the project!) ends 31<sup>st</sup> August 2016
- 2<sup>nd</sup> and final report due 30<sup>th</sup> October 2016 (Sunday) so 28<sup>th</sup> October realistically
- Format largely the same as previous except:
  - Much larger section on ‘use and dissemination of foreground’ papers, conference presentations, outreach, IP protection
  - Certificate of financial statements (external audit) needed for cumulative claims (P1+P2) >€375,000. *Expected to apply to all university partners*



# Funding

- Remember that total amount paid to each partner is based on amounts claimed. If the total budget is not claimed, then the total paid will reduce accordingly.
- Details of the amount remaining to be claimed by each partner was sent with P1 payment notification – please get in touch if you have any queries regarding this ([prediction@dundee.ac.uk](mailto:prediction@dundee.ac.uk))





- Please return your name badges to me before you leave
- Please remember to send me a copy of your presentation (prediction@dundee.ac.uk)
- Thank you very much 😊

# Budget example

- Budget €1,000,000
  - Prefinancing (60%) €600,000
  - P1 accepted claim €300,000
  - P1 payment €300,000
  - P2 accepted claim €700,000
  - P2 payment €100,000
  - Total paid €1,000,000
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- However, if only €650,000 claimed in P2, then P2 payment would be €50,000 and the total paid would be €950,000