



UKPDS Outcomes Model User Manual

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**Version 1.3
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**Produced by the University of Oxford
Diabetes Trials Unit (DTU) and
Health Economics Research Centre (HERC)**

www.dtu.ox.ac.uk/outcomesmodel

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To obtain a copy of the UKPDS Outcomes Model software and a license to use it, please contact:

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For all **queries** concerning the UKPDS Outcomes Model and its appropriate use please read this manual and the web site FAQ (www.dtu.ox.ac.uk/outcomesmodel). If your question remains unanswered, email herc@dphpc.ox.ac.uk. For **technical** enquiries concerning software installation, email outcomes.model@dtu.ox.ac.uk.

Background

The UKPDS Outcomes Model is a computerised simulation designed to estimate Life Expectancy, Quality Adjusted Life Expectancy and costs of complications in people with type 2 diabetes. It uses the equations and algorithms published in the UK Prospective Diabetes Study (UKPDS) paper 68¹ which should be read prior to using this software. Caution should be applied if model results are extrapolated to populations that differ

¹ A model to estimate the lifetime health outcomes of patients with Type 2 diabetes: the United Kingdom Prospective Diabetes Study (UKPDS) Outcomes Model (UKPDS no. 68). PM Clarke, AM Gray, A Briggs, AJ Farmer, P Fenn, RJ Stevens, DR Matthews, IM Stratton, RR Holman. *Diabetologia* 2004; **47**:1747–1759

significantly from that included in the UKPDS or that include ethnic groups other than White Caucasian, Afro-Caribbean or Asian-Indian.

The model was developed using data from patients with newly-diagnosed type 2 diabetes who participated in the UKPDS² and were followed up for between six and twenty years. It predicts likely outcomes using risk factors that include; age, sex, ethnicity, duration of diabetes, height, weight, smoking status, total cholesterol, HDL cholesterol, systolic blood pressure and HbA_{1c}. By default, the model is able to forecast changes over time in smoking status, total cholesterol, HDL cholesterol, systolic blood pressure and HbA_{1c} risk factor levels. However, if any or all of these risk factors have values available at any time points simulated, the model can incorporate them.

The main outputs for the UKPDS Outcomes Model are estimates of Life Expectancy, Quality Adjusted Life Expectancy and costs of complications, all with 95% confidence intervals and with discounting applied if requested. Quality Adjusted Life Expectancy values can also be listed for each year simulated for each subject. The model also outputs cumulative event rates and long term history rates, intermediate outputs which the user may find useful.

Changes in Version 1.3

Corrections

- a) The Smoking status check in the Standalone version has been corrected
- b) The Amputation output in the Standalone version was being written to the IHD file and this has been corrected
- c) The Standalone version now produces cohort outputs
- d) The smoking status for a patient is now estimated once per loop instead of once per patient

New Features

- a) Cumulative Event rate output for events has been replaced with Event rate and Long term history rate
- b) Diabetes Related death has been separated into a separate output sheet from Other death
- c) A new group column has been added to the Inputs sheet after the ID column. This allows outputs of 2 patient groups to be compared. Enter 1 for all patients if not dividing into groups. Please note that any input files previously used for the Standalone model will need this column added.
- d) The Input Checks have been combined into a single sheet

Changes in Version 1.2.1

Corrections

- a) Corrected an issue on page 17 of this manual where the example incorrectly stated that the age entered should be 60. The correct value is 59.

New Features

- a) There is now an option to run the Standalone Implementation of the model without user intervention from the command line and other suitable applications.

² UKPDS 8. Study design, progress and performance. Turner RC, Holman RR, Matthews DR, Oakes SF, Bassett PA, Stratton IM, Cull CA, Manley SE, Frighi V. *Diabetologia* 1991; **34**: 877-890

Changes in Version 1.2

Bug Fixes

- a) Incorrect handling of updated smoking status risk factor values has been fixed. In version 1.1 past smokers (value 1) were treated as current smokers (value 2), and current smokers were treated as a doubling of the smoking effect.
- b) Updated risk factor values are now applied correctly at the end of the year stated, rather than at the start as in version 1.1.

New Features

- a) There is now an option to use any of 100 random number sequences. This allows different random number sequences to be selected and exactly the same sequence to be used repeatedly, as desired.
- b) The 1000 bootstrap parameter sets are always used in the same sequence, with wrap round to the first set if necessary. In version 1.2 the option to choose which bootstrap parameter set is to be used at the start of a model run has been added.
- c) Updated estimated annual risk factor levels generated by the model for each subject are now provided on output worksheets for inspection or can be copied to input sheets for use in further model runs if desired.
- d) A “pre-flight check” option ensures that all of the input data are present and within acceptable ranges BEFORE the model is run.
- e) Worksheet tabs have been coloured for ease of identification (PC version only) as follows:
 - Input worksheets ----- Yellow
 - Run worksheet----- Red
 - Check worksheets----- Salmon
 - Output worksheets ----- Green
 - Risk Factor Output worksheets -- Pink
- f) Input worksheets have been amended so that:
 - Age is no longer checked against duration of diabetes
 - Alphanumeric data can be used in the “ID” column.
- g) Windows Users can now choose a desired location for the install and the shared core dll is placed in the system folder.
- h) In addition to the Microsoft Excel implementation of the UKPDS Outcomes Model a standalone implementation that runs on Windows, Macintosh and Linux platforms has now been provided. This implementation of the UKPDS Outcomes Model can handle an unlimited number of subjects (See Standalone Implementation of the UKPDS Outcomes Model on page 17) and does not require Microsoft Excel.

Installation

The UKPDS Outcomes Model is supplied on a CD containing 6 items, namely:

- *ReadMe.txt*
- *UKPDS Outcomes Manual.pdf*

-
- *UKPDS Outcomes Model Windows setup.exe*
 - *UKPDS Outcomes Model Macintosh.dmg*
 - *outcomes.tar.gz*
 - *Standalone Sample*

The UKPDS Outcomes Model software is installed as follows. The first time the software is used it will request a licence key to be entered. This can be found on the installation CD. Once accepted this will not be asked for again.

Windows Installation

Double click or run the file “*UKPDS Outcomes Model Windows setup.exe*” to install the UKPDS Outcomes Model software. A minimum of 3MB free space needs to be available on windows system drive and a further 5MB in the installation folder. The setup program will allow you to select a folder to install into. The following files are installed in the folder:

- *UKPDSOutcomesModel1.3.xls* is the Microsoft Excel™ workbook in which the UKPDS Outcomes Model is embodied
- *UKPDSOutcomesModel.exe* is the standalone implementation of the UKPDS Outcomes Model
- *OutcomesCore13.dll* which is installed in the windows system folder and must **not** be renamed, moved or amended in any way

A link to the UKPDS Outcomes Model website is provided along with an uninstaller.

Macintosh Installation

Double click or run the file “*UKPDS Outcomes Model Macintosh.dmg*” to mount the disk image. Install the Application by dragging it to the applications folder. The Microsoft Excel implementation of UKPDS Outcomes Model is not currently available for the Macintosh platform.

Linux Installation

Copy the “*outcomes.tar.gz*” and extract the installation files from the archive using the following commands:

```
gunzip outcomes.tar.gz
tar xf outcomes.tar
```

Alternatively you may be able to double-click the archive and drag the outcomes folder to a location of your choice. This folder contains five items, the application “*UKPDSOutcomesModel*”, two folders “*UKPDSOutcomesModel Libs*” and “*Resources*” which must be kept in the same folder as the application, and two example input files “*Sample.outcomes*” and “*Sample_inputs.csv*”.

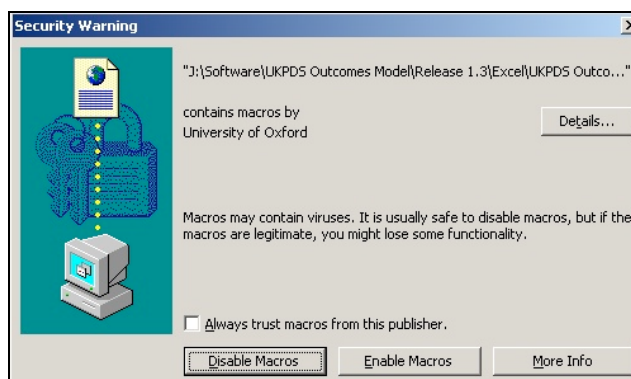
Test the application has been installed correctly by running it and selecting the example input file “*Sample.outcomes*” using the “*File->Open*” menu option. The Microsoft Excel implementation of UKPDS Outcomes Model is not currently available for the Linux platform.

Excel Issues

The UKPDS Outcomes Model requires VBA macros in order to run the model. If they are disabled then the software will not function.

Microsoft Office 2003

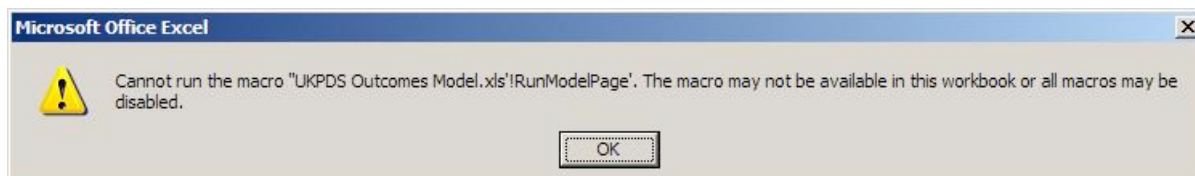
Start Excel, and open UKPDS Outcomes Model v1.3.xls. The following dialog will show



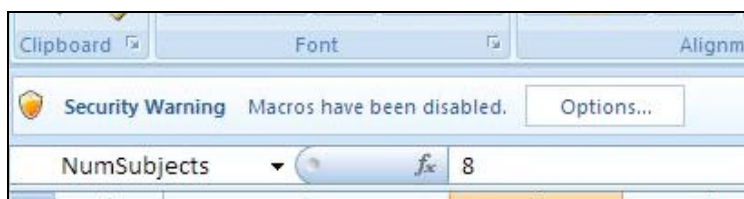
Check the 'Always trust macros from this publisher' box, then click 'Enable Macros'. You will now be able to run the model. When the model is opened again, this dialog will not appear.

Microsoft office 2007

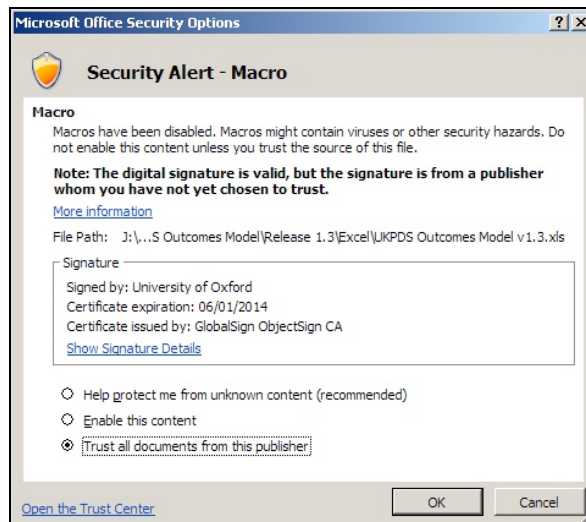
By default Microsoft office 2007 disables VBA macros. Attempting to run the model with macros disabled will result in a dialog similar to this:



In office 2007 you will also see a message like this:



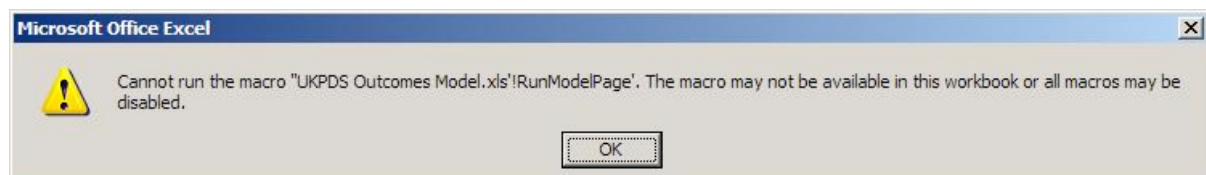
It will be displayed at the top of your worksheet. Clicking the 'Options' button opens the following dialog box:



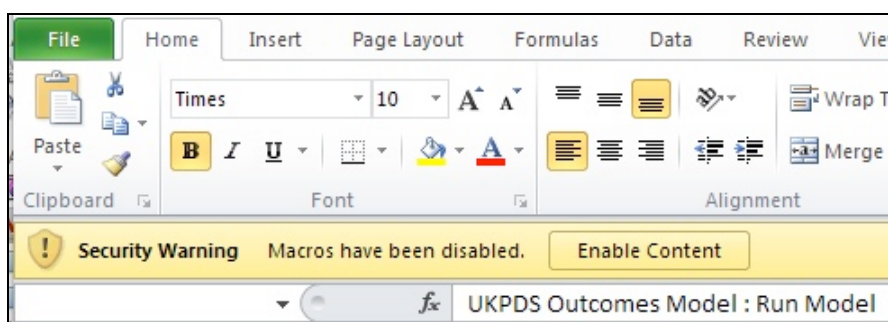
Check the ‘Trust all documents from this publisher’ box, then click OK. You will now be able to run the model. When the model is opened again, this dialog will not appear

Microsoft office 2010

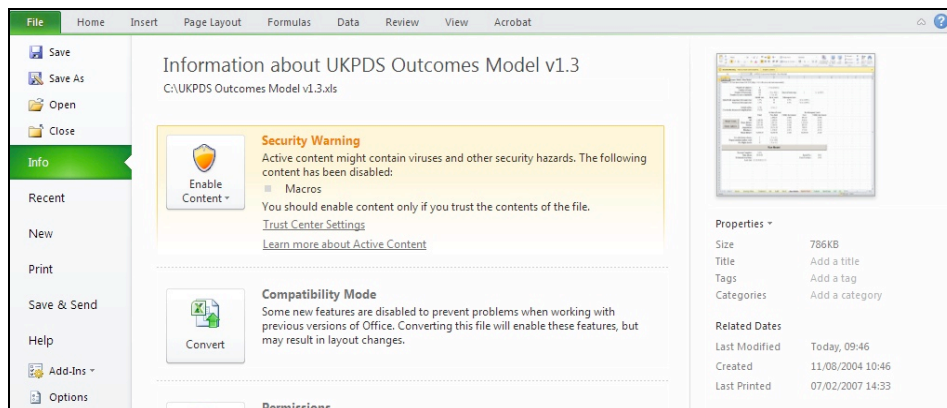
This behaves in the same way as MS Office 2007 in that clicking ‘Run’ will open the following dialog:



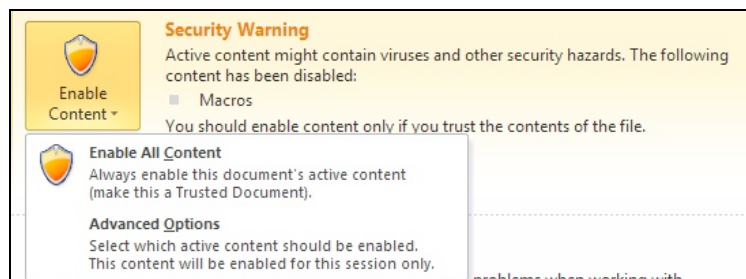
but the security warning at the top of the page looks slightly different:



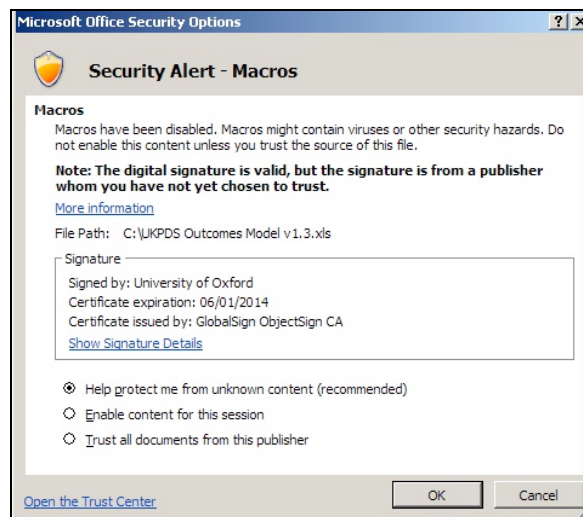
Click **File**. The **Microsoft Office Backstage** view appears. In the **Security Warning** area, on the **Enable Content** button, click the **down-arrow**.



Select **Advanced Options** to learn more about the publisher.



The following **Security Options** dialog will appear



Check the 'Always trust macros from this publisher' box Click OK. You will now be able to run the model. When the model is opened again, this dialog will not appear.

Description of software

The UKPDS Outcomes Model software has been embodied in a Microsoft Excel™ workbook to provide users with a straightforward method for entering or importing details of populations to be evaluated, running the model, viewing the results and the ability to print or export them easily to other software packages. The workbook contains a series of worksheets for the various inputs and outputs, which can be accessed by clicking on the appropriate tab, as follows:

About Worksheet

This contains a brief description of the UKPDS Outcomes Model.

Inputs Worksheet

This worksheet is used to enter patient group, baseline characteristics, risk factor values and history of previous events with one row for each subject. Enter 1 for all patients if not dividing into groups.

ID	Group	Ethnicity	Gender	Age at diagnosis (y)	Duration of diabetes (y)	Weight (kg)	Height (m)	Atrial Fib.	PVD	Smoking*	Chol (mmol/l)	HDL (mmol/l)	Sys BP (mmHg)	HbA1c (%)
001A	1	1	M	60	10	85	1.80	N	N	0	4.00	1.15	125	7.0
002B	1	1	M	60	10	85	1.80	N	N	0	4.00	1.10	130	7.5

Smoking*	Chol (mmol/l)	HDL (mmol/l)	Sys BP (mmHg)	HbA1c (%)	IHD	CHF	Amp	Blind	Renal	Stroke	MI	Discounting start year
0	4.00	1.15	125	7.0	0	0	0	0	0	0	0	0
0	4.00	1.10	130	7.5	0	0	0	0	0	0	0	0

Smoking Status Worksheet

This worksheet is used to enter the smoking status by subject for any or all of the years to be simulated.

ID	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
001A	1				2			1		
002B	0		2			2				

Cholesterol Worksheet

This worksheet is used to enter total cholesterol values (mmol/l) by subject for any or all of the years to be simulated. Ideally these should be from a CDC (Centre for Disease Control) aligned assay.

ID	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Year 11	Ye
001A	6.5	6.5	6.5	6.5	6.5	6.5	6.5					
002B	4.1					5.1						

HDL Worksheet

This worksheet is used to enter HDL cholesterol values (mmol/l) by subject for any or all of the years to be simulated. Ideally these should be from a CDC aligned assay.

SysBP Worksheet

This worksheet is used to enter systolic blood pressure values (mmHg) by subject for any or all of the years to be simulated.

HbA1c Worksheet

This worksheet is used to enter HbA_{1c} values (%) by subject for any or all of the years to be simulated. Ideally these should be from a DCCT (Diabetes Control and Complications Trial) or NGSP (National Glycohemoglobin Standardization Programme) aligned assay.

Run Model Worksheet

This worksheet is used to set run time parameters, including initial and subsequent discount rates, and to run the model. If desired, the default complication-associated costs and utility values can be replaced with user-defined values.

UKPDS Outcomes Model : Run Model						
Version 1.3 © Isis Innovation Ltd 2010 (http://www.dtu.ox.ac.uk/outcomesmodel)						
Number of subjects :	8	(8 available)				
Number of loops :	100					
Number of bootstraps :	500	(0 to 999)		Start at bootstrap :	1 (1 to 999)	
Number of years simulated :	40	(1 to 40)				
	Initial rate	for n years		Subsequent rate		
QALE/Life expectancy discount rate :	3.5%	30	3.0%	(0 to 100%)		
Total costs discount rate :	3.5%	30	3.0%	(0 to 100%)		
Initial utility :	0.785	(0 to 1)				
Cost in the absense of complications :	374.00					
		At time of event		In subsequent years		
		Fatal	Non-fatal	Utility decrement	Cost	Utility decrement
	IHD :		2,696.00	-0.090	891.00	-0.090
Reset Costs	MI :	1,366.00	5,199.00	-0.055	856.00	-0.055
	Heart failure :	3,007.00	3,007.00	-0.108	1,054.00	-0.108
Reset QALEs	Stroke :	4,011.00	3,180.00	-0.164	601.00	-0.164
	Amputation :	10,354.00	10,354.00	-0.280	398.00	-0.280
	Blindness :		1,358.00	-0.074	575.00	-0.074
	Renal failure :	30,000.00	30,000.00	-0.263	30,000.00	-0.263
Use risk factor sheets :	Y	(Y or N)				
Repeat random number seed :	1	(1 to 100)				
Pre-flight check :	N	(Y or N)				
Run Model						
Percent Complete :	100.0%	Run complete				
Time taken :	00:00:27					
Estimated total time :				Serial No :	1956	
				Core Version :	1.302	
Last run :	10/11/2010 11:52					

Inputs Check Worksheet: Subject Characteristics

This worksheet provides the means and standard deviation (SD) or counts by column for Inputs Worksheets parametric or categorical data respectively.

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
UKPDS Outcomes Model : Inputs check														
Version 1.3 © Isis Innovation Ltd 2005 (http://www.dtu.ox.ac.uk/outcomesmodel)														
Subject Characteristics														
	Demographic characteristics							Risk factor values at diagnosis of type 2 diabetes						
		Ethnicity (1,2,3)	Gender (M,F)	Age (y) (Mean,SD,N)	Duration of diabetes (y) (Mean,SD,N)	Weight (kg) (Mean,SD,N)	Height (m) (Mean,SD,N)	Atrial Fib. (Y,N)	PVD (Y,N)	Smoking* (0,1,2)	Chol (mmol/l) (Mean,SD,N)	HDL (mmol/l) (Mean,SD,N)	Sys BP (mmHg) (Mean,SD,N)	HbA1c (%) (Mean,SD,N)
All	Count													
	8	8	4	60.63	10	82.50	1.75	1	1	7	4.03	1.09	133.75	7.71
		0	4	1.65	0	2.5	0.05	7	7	0	0.07	0.07	5.99	0.58
		0		8	8	8	8			1	8	8	8	8
Group 1														
	4	4	4	60.00	10	85.00	1.80	0	0	4	4.00	1.08	132.50	7.75
		0	0	0.00	0	0	0.00	4	4	0	0.00	0.06	5.59	0.56
		0		4	4	4	4			0	4	4	4	4

P	Q	R	S	T	U	V	W	X	Y	Z	AA	AB	
Current risk factor values													Discount (Mean,SD,N)
	Smoking* (0,1,2)	Chol (mmol/l) (Mean,SD,N)	HDL (mmol/l) (Mean,SD,N)	Sys BP (mmHg) (Mean,SD,N)	HbA1c (%) (Mean,SD,N)	IHD (Mean,SD,N)	CHF (Mean,SD,N)	Amp (Mean,SD,N)	Blind (Mean,SD,N)	Renal (Mean,SD,N)	Stroke (Mean,SD,N)	MI (Mean,SD,N)	
	7	4.03	1.09	133.75	7.71	0.13	0.13	0.13	0.13	0.13	0.13	0.13	0.13
	0	0.07	0.07	5.99	0.58	0.33	0.33	0.33	0.33	0.33	0.33	0.33	0.33
	1	8	8	8	8	8	8	8	8	8	8	8	8
	4	4.00	1.08	132.50	7.75	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	0	0.00	0.06	5.59	0.56	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	0	4	4	4	4	4	4	4	4	4	4	4	4

Inputs Check Worksheet: Smoking Status Check

This section provides counts of the number of “0”, “1” or “2” smoking status values by simulated year.

Smoking status check by simulated year											
All	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	
0s	1	0	0	0	0	0	0	0	0	0	
1s	1	0	0	0	0	0	0	1	0	0	
2s	1	0	2	1	2	1	0	0	0	0	
Group 1											
0s	1	0	0	0	0	0	0	0	0	0	
1s	1	0	0	0	0	0	0	1	0	0	
2s	1	0	1	0	1	1	0	0	0	0	
Group 2											

Inputs Check Worksheet: Cholesterol Check

This section provides the means, standard deviations and count (n) for total cholesterol values by simulated year.

Cholesterol check by simulated year											
All	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	
Mean	5.30	6.50	6.50	6.50	6.50	5.80	6.50				
SD	1.20	0.00	0.00	0.00	0.00	0.70	0.00				
N	4	2	2	2	2	4	2	0	0	0	
Group 1											
Mean	5.30	6.50	6.50	6.50	6.50	5.80	6.50				
SD	1.20					0.70					
N	2	1	1	1	1	2	1	0	0	0	
Group 2											

Inputs Check Worksheet: HDL Check

This section provides the means, standard deviations and count (n) for HDL cholesterol values by simulated year.

Inputs Check Worksheet: SysBP Check

This section provides the means, standard deviations and count (n) for systolic blood pressure values by simulated year.

Inputs Check Worksheet: HbA1c Check

This worksheet provides the means, standard deviations and count (n) for HbA_{1c} values by simulated year.

Outputs Worksheet

This worksheet tabulates Life Expectancy, Quality Adjusted Life Expectancy and cumulative complication costs, together with their respective 95% confidence intervals, for each subject specified. Overall values for the population are provided as well as Quality Adjusted Life Expectancy values and costs by subject for each year simulated.

A	B	C	D	E	F	G	H	I	J			
UKPDS Outcomes Model : Outputs					Last run : 21/10/2010 12:25							
Version 1.3 © Isis Innovation Ltd 2005 (http://www.dtu.ox.ac.uk/outcomesmodel)												
ID	Life expectancy	95% CI		Total QALE	95% CI		Total cost of complications	95% CI				
		Lower	Upper		Lower	Upper		Lower	Upper			
All:	9.1	8.1	10.1	6.9	6.2	7.6	6417.61	4376.90	8458.32			
Group 1:	8.6	7.6	9.5	6.5	5.8	7.2	6335.24	4202.08	8468.40			
Group 2:	9.6	8.4	10.8	7.4	6.5	8.2	6499.98	3994.74	9005.22			
Difference:	-1.074	-1.9	-0.2	-0.877	-1.5	-0.2	-164.738	-2399.7	2070.2			
001A	8.9	7.7	10.1	6.8	5.9	7.7	6585.00	3889.8	9280.2			
002B	8.3	7.1	9.5	6.3	5.4	7.2	5200.23	2062.6	8337.8			
▶ \ \ Outputs \ \ Bootstraps \ \ IHD \ MI \ \ Heart failure \ \ Stroke \ \ Amputation \ \ Blindness \ \ Renal Failure < >												
K	L	M	N	O	P	Q	R	S	T	U	V	W
Expected utility by simulated year												
Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Year 11	Year 12	Year 13
0.771	0.719	0.668	0.620	0.573	0.529	0.478	0.422	0.373	0.329	0.285	0.244	0.208
0.771	0.717	0.667	0.613	0.560	0.511	0.458	0.397	0.343	0.297	0.251	0.211	0.174
0.772	0.720	0.670	0.627	0.585	0.547	0.499	0.447	0.404	0.361	0.318	0.277	0.241
-0.001	-0.003	-0.004	-0.013	-0.025	-0.036	-0.042	-0.050	-0.061	-0.064	-0.067	-0.067	-0.067
0.780	0.723	0.667	0.620	0.570	0.531	0.477	0.412	0.372	0.331	0.283	0.232	0.197
0.771	0.726	0.694	0.636	0.574	0.506	0.443	0.384	0.331	0.287	0.240	0.198	0.157
▶ \ \ Outputs \ \ Bootstraps \ \ IHD \ MI \ \ Heart failure \ \ Stroke \ \ Amputation \ \ Blindness \ \ Renal Failure < >												
AY	AZ	BA	BB	BC	BD	BE	BF	BG	BH	BI	BJ	BK
Total cost by simulated year												
Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Year 11	Year 12	Year 13
455.024	454.414	450.285	450.635	441.510	410.134	457.804	395.014	364.746	407.468	373.100	321.668	258.421
445.805	474.923	495.518	481.164	459.156	402.652	415.145	399.330	350.949	402.014	372.221	332.507	288.861
464.243	433.906	405.053	420.107	423.864	417.617	500.464	390.698	378.543	412.923	373.979	310.828	227.991
-18.438	41.017	90.465	61.057	35.292	-14.965	-85.319	8.631	-27.594	-10.909	-1.757	21.679	60.873
443.600	546.338	423.879	344.425	450.204	364.659	314.422	349.546	253.799	503.457	511.180	446.523	355.110
444.700	353.749	383.337	581.446	324.142	403.886	337.810	461.770	375.096	283.532	266.699	198.908	128.247
▶ \ \ Outputs \ \ Bootstraps \ \ IHD \ MI \ \ Heart failure \ \ Stroke \ \ Amputation \ \ Blindness \ \ Renal Failure < >												

Bootstraps Worksheet

This worksheet tabulates estimated mean Life Expectancy, QALYS and complication costs by bootstrap replication. The number of results reported depends on the number of bootstrap replications requested with each result showing the mean value for that bootstrap averaged across the total number of loops (Monte Carlo trials) requested.

A	B	C	D	E	F	G	H	I	J	K	L	M
UKPDS Outcomes Model : Bootstraps												
Version 1.3 © Isis Innovation Ltd 2005 (http://www.dtu.ox.ac.uk/outcomesmodel)												
Bootstrap Number	All			Group 1			Group 2			Difference		
	Life expectancy	Total QALE	Total cost of complications	Life expectancy	Total QALE	Total cost of complications	Life expectancy	Total QALE	Total cost of complications	Life expectancy	Total QALE	Total cost of complications
1	8.4	6.5	5,169.25	7.6	5.8	4,779.08	9.2	7.1	5,539.41	-1.6	-1.3	-780.32
2	8.5	6.4	5,744.80	8.0	6.0	5,984.52	9.0	6.9	5,505.08	-1.0	-0.8	479.44
▶ \ \ Cholesterol \ HDL \ SysBP \ HbA1c \ Run Model \ Inputs Check \ Outputs \ Bootstraps \ IHD \ MI \ \ Heart failure \ \ Stroke \ \ Amputation \ \ Blindness < >												

IHD (Ischaemic Heart Disease), MI (Myocardial Infarction), Heart failure, Stroke, Amputation, Blindness, Renal failure, Diabetes related death, Other death, All death Worksheets

These worksheets show the expectation by year that a subject experienced an event of these types (IHD example shown). This value is calculated by dividing the total simulated instances where a subject has previously had an event and is still alive by the total number of loops (Monte Carlo trials). Note that a subject may have events such as a myocardial infarction in a particular year as well as a diabetes related death, as these events are not mutually exclusive.

A	B	C	D	E	F	G	H	I	J	K
UKPDS Outcomes Model : IHD events										
Version 1.3 © Isis Innovation Ltd 2005 (http://www.dtu.ox.ac.uk/outcomesmodel)										
Event rate by simulated year (point estimate)										
ID	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
All:	0.003	0.006	0.008	0.008	0.006	0.009	0.008	0.006	0.006	0.000
Group 1:	0.003	0.005	0.013	0.010	0.005	0.013	0.003	0.013	0.010	0.000
Group 2:	0.003	0.008	0.003	0.005	0.008	0.005	0.013	0.000	0.003	0.000
Difference:	0.000	-0.003	0.010	0.005	-0.003	0.008	-0.010	0.013	0.008	0.000
001A	0.010	0.010	0.030	0.000	0.000	0.000	0.000	0.010	0.000	0.000
002B	0.000	0.000	0.000	0.030	0.000	0.000	0.000	0.000	0.020	0.000

Also shown is the expectation of the subject being still alive with a long term history of the event (see IHD example below). This value is calculated by dividing the total simulated number of events by the total number of loops (Monte Carlo trials) where the subject is alive.

DR	DS	DT	DU	DV	DW	DX	DY	DZ	EA	EB	EC
Long term history rate by simulated year (point estimate)											
Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Year 11	Year 12
0.003	0.009	0.016	0.023	0.029	0.038	0.041	0.045	0.050	0.045	0.050	0.048
0.003	0.008	0.020	0.028	0.033	0.045	0.048	0.055	0.063	0.055	0.058	0.053
0.003	0.010	0.013	0.018	0.025	0.030	0.035	0.035	0.038	0.035	0.043	0.043
0.000	-0.003	0.008	0.010	0.008	0.015	0.013	0.020	0.025	0.020	0.015	0.010
0.010	0.020	0.050	0.050	0.050	0.050	0.050	0.060	0.060	0.060	0.060	0.060
0.000	0.000	0.000	0.020	0.020	0.020	0.020	0.040	0.060	0.040	0.050	0.040

Estimated Smoking Status Worksheet

This worksheet shows smoking status values by simulated year, as estimated by the UKPDS Outcomes Model. If updated smoking status values are provided as inputs, they are reproduced in this worksheet.

UKPDS Outcomes Model : Estimated smoking status (0=Non-smoker, 1=Current smoker of tobacco) by simulated year												
Version 1.3 © Isis Innovation Ltd 2010 (http://www.dtu.ox.ac.uk/outcomesmodel)												
ID	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Year 11	Year 12
001A	0	0	0	0	2	0	0	0	0	0	0	0
002B	0	0	2	2	2	2	2	2	0	0	0	0
003C	2	2	0	0	0	0	0	0	0	0	0	0

Estimated Lipid Ratio Worksheet

This worksheet shows lipid ratio (total to HDL cholesterol) values by simulated year, as estimated by the UKPDS Outcomes Model. If updated risk total and HDL cholesterol values are provided as inputs, their ratios are reproduced in this worksheet.

UKPDS Outcomes Model : Estimated lipid ratio (mmol/l) by simulated year													
Version 1.3 © Isis Innovation Ltd 2010 (http://www.dtu.ox.ac.uk/outcomesmodel)													
ID	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Year 11	Year 12	
001A	7.22222222	7.22222222	7.22222222	7.22222222	7.22222222	7.22222222	7.22222222	7.22222222	5.8158932	5.0760273	4.6867858	4.4820069	4.35
002B	3.72727272	4.0170925	4.1695659	4.2497818	4.2919831	4.6363636	4.4953628	4.4211826	4.3821567	4.3616252	4.3508236	4.3	
003C	4.1040458	4.258993	4.3405103	4.3833964	4.4059586	4.4178285	4.4240733	4.4273586	4.429087	4.4299963	4.4304747	4.4	

Estimated SysBP

This worksheet shows systolic blood pressure values by simulated year, as estimated by the UKPDS Outcomes Model. If updated systolic blood pressure values are provided as inputs they are reproduced in this sheet.

Estimated HbA_{1c}

This worksheet shows HbA_{1c} values by simulated year, as estimated by the UKPDS Outcomes Model. If updated HbA_{1c} values are provided as inputs they are reproduced in this sheet.

It is essential that:

- Workbook worksheets are not rearranged in any way.
- Columns are not reordered.

Note: All output sheets are cleared each time the model is run.

Entering Population Information

Enter data for subjects by typing it directly into the appropriate *Inputs* worksheet cells or by copying and pasting it from other software applications. No results will be produced for subjects that have missing data items. It is the responsibility of the user to ensure that only valid values are entered as the software applies few data entry checks. The workbook supplied contains sample data from 8 hypothetical subjects for the user to experiment with or to replace with their own data.

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
UKPDS Outcomes Model : Inputs														
Version 1.3 © Isis Innovation Ltd 2005 (http://www.dtu.ox.ac.uk/outcomesmodel)														
Subject Characteristics * Smoking: 0=Never, 1=Past smoker or 2=Current smoker of tobacco														
ID	Group	Demographic characteristics						Risk factor values at diagnosis of type 2 diabetes						
		Ethnicity	Gender	Age at diagnosis (y)	Duration of diabetes (y)	Weight (kg)	Height (m)	Atrial Fib.	PVD	Smoking*	Chol (mmol/l)	HDL (mmol/l)	Sys BP (mmHg)	HbA1c (%)
001A	1	1	M	60	10	85	1.80	N	N	0	4.00	1.15	125	7.0
002B	1	1	M	60	10	85	1.80	N	N	0	4.00	1.10	130	7.5
003C	1	1	M	60	10	85	1.80	N	N	0	4.00	1.05	135	8.0
004D	1	1	M	60	10	85	1.80	N	N	0	4.00	1.00	140	8.5
005E	2	1	F	60	10	80	1.70	N	N	0	4.00	1.15	125	7.0
006F	2	1	F	60	10	80	1.70	N	N	0	4.00	1.10	130	7.5
007G	2	1	F	60	10	80	1.70	N	N	0	4.00	1.05	135	8.0
008H	2	1	F	60	10	80	1.70	N	N	0	4.00	1.00	140	8.5

The items³ that need to be provided for each subject are:

ID Subject identifier (optional)

Demographic characteristics

Ethnicity 1=White-Caucasian, 2=Afro-Caribbean, 3=Asian-Indian

Group 1 or 2 to compare subject groups. Enter 1 if not comparing subject groups

Gender M=Male, F=Female

Age Age in years at diagnosis of diabetes

Dur Duration in years since diagnosis of diabetes

Weight Weight in kilograms at diagnosis of diabetes [1.0 Kg = 2.2 pounds]

Height Height in metres at diagnosis of diabetes [1.0 metre = 39 inches]

Risk factor values at diagnosis of type 2 diabetes

Atrial Fib Presence of atrial fibrillation (Y=Yes, N=No)

PVD Presence of peripheral vascular disease (Y=Yes, N=No)

Smoking Smoking status (0=Never, 1=Past smoker, 2=Current smoker of tobacco)

Chol Total cholesterol (mmol/l) [1.0 mmol/l = 38.6 mg/dl]

HDL HDL cholesterol (mmol/l) [1.0 mmol/l = 38.6 mg/dl]

SysBP Systolic blood pressure (mm Hg)

HbA1c HbA_{1c} (%)

Current risk factor values (leave blank if data not available)

Smoking Smoking status (0=Never, 1=Past smoker, 2=Current smoker of tobacco)

Chol Total cholesterol (mmol/l) [1.0 mmol/l = 38.6 mg/dl]

HDL HDL cholesterol (mmol/l) [1.0 mmol/l = 38.6 mg/dl]

SysBP Systolic blood pressure (mm Hg)

HbA1c HbA_{1c} (%)

Years since pre-existing event

³ Full definitions of the input variables used are given in UKPDS paper 68.

IHD	Time in years since first diagnosis of ischaemic heart disease (0 if none)
CHF	Time in years since first diagnosis of chronic heart failure (0 if none)
Amp	Time in years since first amputation (0 if none)
Blind	Time in years since first diagnosed blind in one eye (0 if none)
Renal	Time in years since first diagnosed with renal failure (0 if none)
Stroke	Time in years since first stroke (0 if none)
MI	Time in years since first myocardial infarction (0 if none)
Discounting start year	The year of the simulation discounting of costs and outcomes commences. The ability to set this is useful when a simulation is run that contains actual follow-up data for the subjects specified.

Running the Model

The *Run Model* worksheet is used to set the following parameters and then to start the simulation.

UKPDS Outcomes Model : Run Model						
Version 1.3 © Isis Innovation Ltd 2010 (http://www.dtu.ox.ac.uk/outcomesmodel)						
Number of subjects :	8	(8 available)				
Number of loops :	100					
Number of bootstraps :	500	(0 to 999)	Start at bootstrap :	1	(1 to 999)	
Number of years simulated :	40	(1 to 40)				
	Initial rate	for n years	Subsequent rate			
QALE/Life expectancy discount rate :	3.5%	30	3.0%		(0 to 100%)	
Total costs discount rate :	3.5%	30	3.0%		(0 to 100%)	
	Initial utility :	0.785			(0 to 1)	
Cost in the absence of complications :	374.00					
		At time of event		In subsequent years		
		Fatal	Non-fatal	Utility decrement	Cost	Utility decrement
	IHD :		2,696.00	-0.090	891.00	-0.090
Reset Costs	MI :	1,366.00	5,199.00	-0.055	856.00	-0.055
	Heart failure :	3,007.00	3,007.00	-0.108	1,054.00	-0.108
Reset QALEs	Stroke :	4,011.00	3,180.00	-0.164	601.00	-0.164
	Amputation :	10,354.00	10,354.00	-0.280	598.00	-0.280
	Blindness :		1,358.00	-0.074	575.00	-0.074
	Renal failure :	30,000.00	30,000.00	-0.263	30,000.00	-0.263
	Use risk factor sheets :	Y				(Y or N)
	Repeat random number seed :	1				(1 to 100)
	Pre-flight check :	N				(Y or N)
Run Model						
	Percent Complete :	100.0%	Run complete			
	Time taken :	00:00:27			Serial No :	1956
	Estimated total time :				Core Version :	1.302
	Last run :	10/11/2010 11:52				

Number of subjects Sets the number of subjects to be included in the simulation. (number with data available shown alongside).

Number of loops Sets the number of internal loops or Monte-Carlo trials per subject, to reduce Monte-Carlo error (sometimes termed variability or first order uncertainty). The predicted outcome for each subject varies with each Monte-Carlo trial but will stabilise if a sufficient number of Monte-Carlo simulations are performed. This is done by running the simulation repeatedly on the same patient but with different sets of random numbers. Performing more loops will produce more stable predicted outcomes for each subject but will take longer. At least 1,000

	loops are required to obtain stable estimates for subjects. A minimum of 100 may be appropriate when looking at overall values for a cohort.
Number of bootstraps	Sets the number of bootstraps to address parameter uncertainty (sometimes termed second order uncertainty) and estimate confidence intervals around Life Expectancy, Quality Adjusted Life Expectancy and complication costs estimates. The software contains full sets of model equation parameters derived from bootstrap samples of the UKPDS trial population which were generated by sampling with replacement from the original data set. When the desired number of bootstraps has been chosen, each bootstrap run will use a different set of model equation parameters, drawing from those available. The current version of the software is limited to a maximum of 1,000 bootstraps. Ideally 1,000 bootstraps should be specified although 100 may be sufficient to obtain approximate confidence intervals estimates. If the number of bootstraps is set to 0 or 1 then no confidence intervals will be generated.
Start at bootstrap	Sets which of the 1000 bootstrap parameters sets supplied should be used first. Parameter sets are used in order, with wrap round to the first set if necessary.
Number of years simulated	Sets the maximum possible number of years simulated per subject. The time taken to run the model can be reduced by not specifying more years to be simulated than required. The current version of the software is limited to a maximum of 40 years.
Discount rates	Sets the annual discount rate to be applied to Life Expectancy, Quality Adjusted Life Expectancy and complication costs estimates. Two different discount rates can be applied, for example, a discount rate of 3% can be specified for the first 10 years and then 1.5% for all subsequent years. If discounting is not required enter "0".
Initial Utility value	Sets the utility value for a subject without any complications. Used in the calculation of QALYs.
Cost in the absence of complications	Sets the annual cost incurred by a subject without any of the complications simulated in the model.
Utility Decrements	Sets utility decrements for each of seven diabetes-related complications (IHD, MI, Heart Failure, stroke, amputation, blindness) in the year in which they occur (At time of event) and thereafter (In subsequent years). The default values are taken from UKPDS paper 62 ⁴ except for renal failure ⁵ . If the

⁴ Philip Clarke, Alastair Gray & Rury Holman Estimating utility values for health states of type 2 diabetic patients using the EQ-5D (UKPDS 62) Medical Decision Making (2002); 22: 340-349

⁵ Kiberd BA & Jindal KK. Screening to prevent renal failure in insulin dependent diabetic patients: an economic evaluation BMJ 1995; 311 (702) 1595-1599

user has utility decrements for subsequent years they can be entered in the next column.

Cost

The health care costs associated with each fatal or non-fatal diabetes-related complication are listed in columns C & D, *i.e.* the acute costs. The costs that accrue in all subsequent years are listed in column F. The default costs are derived from UKPDS paper 65⁶ updated to 2004 prices using the Hospital and Health Services Price Index and reflect health care resource use in the United Kingdom in year 2000. Other costs can be entered by the user.

Reset Costs

Click this button to revert to default Costs as supplied with this version of the Outcomes Model.

ResetQALES

Click this button to revert to the default QALE decrements as supplied with this version of the Outcomes Model.

Use risk factor sheets

Allows user to specify incorporation of data for risk factor entry worksheets. The model will forecast values for any missing data.

Random number sequence Sets which of the 100 random number sequences available is to be used.

Pre-flight check This option ensures that all of the input data are present and within acceptable ranges BEFORE the simulation is run.

Run Model

Click this button to start the simulation.

Percent Complete

Provides an indication of progress.

Time taken

Provides an indication of elapsed time taken.

Estimated time remaining Provides an indication of the estimated time to completing all simulations. The model can be stopped at any time by holding down the control key and pressing the break key.

Outputs Worksheet

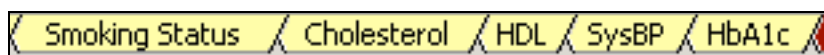
This worksheet displays the Life Expectancy, Quality Adjusted Life Expectancy and complication cost estimates for each subject, together with their respective 95% confidence intervals. The overall results for the population simulated are shown in the first row of the table.

A	B	C	D	E	F	G	H	I	J
UKPDS Outcomes Model : Outputs				Last run : 21/10/2010 12:25					
Version 1.3 © Isis Innovation Ltd 2005 (http://www.dtu.ox.ac.uk/outcomesmodel)									
ID	Life expectancy	95% CI		Total QALE	95% CI		Total cost of complications	95% CI	
		Lower	Upper		Lower	Upper		Lower	Upper
All:	9.1	8.1	10.1	6.9	6.2	7.6	6417.61	4376.90	8458.32
Group 1:	8.6	7.6	9.5	6.5	5.8	7.2	6335.24	4202.08	8468.40
Group 2:	9.6	8.4	10.8	7.4	6.5	8.2	6499.98	3994.74	9005.22
Difference:	-1.074	-1.9	-0.2	-0.877	-1.5	-0.2	-164.738	-2399.7	2070.2
001A	8.9	7.7	10.1	6.8	5.9	7.7	6585.00	3889.8	9280.2
002B	8.3	7.1	9.5	6.3	5.4	7.2	5200.23	2062.6	8337.8

⁶ Clarke P, Gray A, Legood R, Briggs A & Holman R. The impact of diabetes-related complications on healthcare costs: results from the United Kingdom Prospective Diabetes Study (UKPDS 65). *Diabetic Medicine* 2003; 20 (6): 442-50

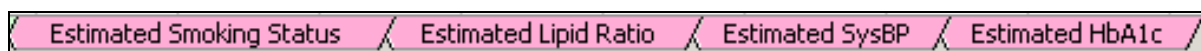
K	L	M	N	O	P	Q	R	S	T	U	V	W
Expected utility by simulated year												
Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Year 11	Year 12	Year 13
0.771	0.719	0.668	0.620	0.573	0.529	0.478	0.422	0.373	0.329	0.285	0.244	0.208
0.771	0.717	0.667	0.613	0.560	0.511	0.458	0.397	0.343	0.297	0.251	0.211	0.174
0.772	0.720	0.670	0.627	0.585	0.547	0.499	0.447	0.404	0.361	0.318	0.277	0.241
-0.001	-0.003	-0.004	-0.013	-0.025	-0.036	-0.042	-0.050	-0.061	-0.064	-0.067	-0.067	-0.067
0.780	0.723	0.667	0.620	0.570	0.531	0.477	0.412	0.372	0.331	0.283	0.232	0.197
0.771	0.726	0.694	0.636	0.574	0.506	0.443	0.384	0.331	0.287	0.240	0.198	0.157
▶ \ Outputs \ Bootstraps \ IHD \ MI \ Heart failure \ Stroke \ Amputation \ Blindness \ Renal Failure < >												
AY	AZ	BA	BB	BC	BD	BE	BF	BG	BH	BI	BJ	BK
Total cost by simulated year												
Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Year 11	Year 12	Year 13
455.024	454.414	450.285	450.635	441.510	410.134	457.804	395.014	364.746	407.468	373.100	321.668	258.421
445.805	474.923	495.518	481.164	459.156	402.652	415.145	399.330	350.949	402.014	372.221	332.507	288.861
464.243	433.906	405.053	420.107	423.864	417.617	500.464	390.698	378.543	412.923	373.979	310.828	227.991
-18.438	41.017	90.465	61.057	35.292	-14.965	-85.319	8.631	-27.594	-10.909	-1.757	21.679	60.873
443.600	546.338	423.879	344.425	450.204	364.659	314.422	349.546	253.799	503.457	511.180	446.523	355.110
444.700	353.749	383.337	581.446	324.142	403.886	337.810	461.770	375.096	283.532	266.699	198.908	128.247
▶ \ Outputs \ Bootstraps \ IHD \ MI \ Heart failure \ Stroke \ Amputation \ Blindness \ Renal Failure < >												

Annual Risk Factor Values



Input worksheets are provided where values for each year to be simulated can be entered for smoking status, total cholesterol, HDL cholesterol, systolic blood pressure and HbA_{1c} if desired. If no values are entered the software will forecast values by default. The use of these annual risk factor values can be selected or deselected for any run on the *Run Model* sheet.

Annual Estimated Risk Factor Values



These output sheets display the updated estimated annual risk factor levels for individual subjects. Data from these sheets can be used to populate the annual risk factor values sheets by copying and pasting. To use the estimated annual lipid ratio data in this fashion, copy the values to the Cholesterol worksheet and set all values in the HDL worksheet to 1.

Worked Examples

Example #1

To determine the likely impact of a fixed difference in HbA_{1c} values over time, say 11.0% versus 7.0%, on Life Expectancy and Quality Adjusted Life Expectancy for a sixty-year old patient with type 2 diabetes of one year's duration, proceed as follows:

Step 1

Using the *Inputs* sheet, enter characteristics for two patients that have identical risk-factor levels e.g.:

Demographic characteristics

Group	1
Ethnicity	1 (White)
Gender	M (Male)
Age at diagnosis	59 (years)
Duration of diabetes	1 (year)
Weight	100 (Kg)
Height	1.74 (metres)
<i>Risk factor values at diagnosis of type 2 diabetes</i>	
Atrial Fib	N (No)
PVD	N (No)
Smoking	0 (Never smoked)
Chol	4.0 (mmol/l)
HDL	1.0 (mmol/l)
SysBP	120 (mm Hg)
HbA_{1c}	11.0 (%) for subject one
HbA_{1c}	7.0 (%) for subject two

Current risk factor values

Smoking	0 (Never smoked)
Chol	4.0 (mmol/l)
HDL	1.0 (mmol/l)
SysBP	130 (mm Hg) <i>Note, the value is higher than at diagnosis</i>
HbA_{1c}	11.0 (%) for subject one
HbA_{1c}	7.0 (%) for subject two
Start of discounting	0 for both subjects

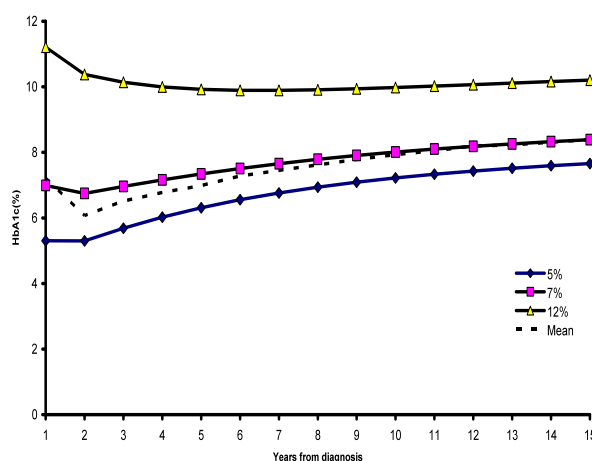
Step 2

Go to the *Run Model* sheet. To obtaining point estimates in an initial simulation we will deal only with Monte Carlo error. Set the "Number of subjects" to 2, the "Number of loops" to 10,000 to reduce Monte Carlo error, the "Maximum years simulated" to 40 and the "Discount rate" to 0. At this stage we will not estimate confidence intervals so set the "Number of bootstraps" to 0. Set the 'Use risk factor sheets' to N.

Step 3

Run the model and then look at the *Outputs* sheet. The Life Expectancy for subject one should be approximately 16.6 years (12.3 QALEs) and for subject two, with the lower HbA_{1c}, somewhat greater at approximately 17.5 years (13.1 QALEs). Estimates may differ slightly between simulations as the Outcomes model may have used a different set of random

numbers. To produce these estimates the model has forecast values for smoking status, total & HDL cholesterol, systolic blood pressure and HbA_{1c} for each year simulated, based on the current risk factor values entered. The time paths for the risk factor equations used are those plotted below from figure 3 of UKPDS paper 68². It can be seen that subjects with high initial HbA_{1c} levels will tend to have lower values over time whereas those with low levels initially will tend to have higher values over time.



It is also possible to examine cumulative event rates (adjusted for death as competing risk) over the years specified in the simulation. For example, the MI sheet contains the expected incidence of myocardial infarction for both groups. The cumulative incidence up to year X is estimated by adding the ‘event rate by simulated year’ up to year X. For example, the expected cumulative number of events plateau at around 0.47 for patient one and 0.42 for patient two around 30th year of the simulation as almost all patients are dead and therefore cannot have an MI.

Example #2

We may also want to undertake a simulation based on a different assumed future time path for HbA_{1c} values instead of following the default paths. To undertake this type of simulation proceed as follows:

Step 1

Go to the *HbA1c* sheet. For the first subject, enter 11.0 for year 1 and copy this value across the row to year 40. Repeat this for process for the second subject, entering 7.0 instead of 11.0.

Step 2

Go to the *Run Model* sheet. Change “Use risk factor sheets” from N to Y to indicate the model is to use the values specified for each year simulated.

Step 3

Run the model and then look at the *Outputs* sheet. Subject one’s Life Expectancy will now be somewhat less, at around 16.0 years, as his HbA_{1c} has remained elevated at its initial value of 11.0%. Subject two will have an extended Life Expectancy, of around 17.7 years, as his HbA_{1c} has remained low rather than tending to rise over time.

Example #3

To obtain confidence intervals for Life Expectancy and Quality of Life Expectancy estimates proceed as follows:

Step 1

Go to the *Run Model* sheet. Set the “Number of loops” to 1,000 and the “Number of bootstraps” to 1,000. Run the model. The simulation will take a little longer to run (approximately 20 minutes on PC with a Pentium IV processor). Go to the *Outputs* sheet. The Life Expectancy and Quality of Life Expectancy estimates will now have 95% confidence intervals around them.

Example #4

To compare the impact of different risk factor profiles on two groups of subjects, enter the population characteristics for group one and group two. Run the model. Go to the *Outputs* sheet. The average life years, quality adjusted life expectancy and costs are provided for all patients (‘All’ row) and for each of the two groups. The incremental life-years, quality adjusted life years and costs are provided in the ‘Difference’ row.

Standalone Implementation of the UKPDS Outcomes Model

This implementation of the UKPDS Outcomes Model is a standalone program that does not require Microsoft Excel and can handle an unlimited number of subjects.

When the program is started the user is presented with a dialog box, which is the equivalent of the *Run Model* worksheet in the Excel implementation. This is used to set the program parameters and to start a simulation.

The screenshot shows the 'UKPDS Outcomes Model version 1.3' dialog box. It has a menu bar with 'File' and 'Edit'. The main area contains several sections of input fields:

- Simulation Parameters:**
 - Number of loops: 1000
 - Number of bootstraps: 10 (0 to 999)
 - Number of years simulated: 40 (1 to 40)
 - Pre-flight check:
 - Start at bootstrap: 1 (1 to 999)
 - Use risk factor files:
- Discount Rates:**
 - Initial rate: 3.5
 - for n years: 30
 - Subsequent rate: 3.0
 - Total costs discount rate: 3.5
 - for n years: 30
 - Subsequent rate: 3.0
- Utility and Cost Parameters:**
 - Initial utility: 0.785
 - Random number sequence: 1 (1 to 100)
 - Cost in the absense of complications: 374.00
- Event Outcomes Table:**

	At time of event			In subsequent years	
	Fatal	Non-fatal	Utility decrement	Cost	Utility decrement
IHD :		2696.00	-0.090	891.00	-0.090
MI :	1366.00	5199.00	-0.055	856.00	-0.055
Heart failure :	3007.00	3007.00	-0.108	1054.00	-0.108
Stroke :	4011.00	3180.00	-0.164	601.00	-0.164
Amputation :	10354.00	10354.00	-0.280	598.00	-0.280
Blindness :		1358.00	-0.074	575.00	-0.074
Renal failure :	30000.00	30000.00	-0.263	30000.00	-0.263
- Buttons:** 'Reset Costs', 'Reset QALEs', 'Cancel Run', 'Run model'.
- Status Indicators:**
 - Percent complete: 0.00%
 - Time taken:
 - Estimated total time:
 - Number of subjects:
 - Serial no:
 - Core version:

The standalone implementation of the UKPDS Outcomes Model reads inputs required from individual data files rather than worksheets in a Microsoft Excel workbook. Similarly, each set of program outputs are written to separate data files. This implementation of the UKPDS Outcomes Model uses a comma separated values (CSV) format for both input and output data files.

Once the parameters for running a particular simulation have been entered they must be saved to a file before the model can be run. By convention, the parameter set filename {name} is used as prefix identifier for files related to this particular simulation. For example, if the parameter set file is 'Sample' it will be saved as 'Sample.outcomes' and the program will look to read patient characteristics from a file called 'Sample_Inputs.csv', smoking status data from 'Sample_SmokingStatus.csv' etc.

Previously saved parameter set files can be loaded, amended and saved under a different filename in order to run different simulations. Parameter set files must only be modified using the standalone implementation of the UKPDS Outcomes Model to preserve their integrity.

CSV File Format

Each row in UKPDS Outcomes Model CSV files contains data for one subject. Data items within each row must be separated by a comma, and rows by a carriage return (line feed is optional). Each row within the file must contain a complete set of the data items required for the file in question. Missing values are indicated simply by leaving nothing between concomitant delimiters.

Input files

An “Inputs” file is essential but files for risk factor value changes over time are optional. No heading rows should be used in input files.

{name}_Inputs.csv

This file contains the following items.

ID	An identifier for the subject
Group	1 or 2 to identify groups of patients for comparison
Ethnicity	Ethnic group (1=White, 2= Afro-Caribbean, 3= Asian-Indian)
Gender	Gender (M=Male, F=Female)
Age	Age in years
Duration of diabetes	Duration of Diabetes in years
Weight	Weight in kg
Height	Height in metres
Diagnosis Atrial Fib.	(Y=Yes, N=No)
Diagnosis PVD	(Y=Yes, N=No)
Diagnosis Smoking	Smoking status at diagnosis (0=Never, 1=Past smoker or 2=Current smoker of tobacco)
Diagnosis Chol	Cholesterol in mmol/l
Diagnosis HDL	HDL Cholesterol in mmol/l
Diagnosis Sys BP	Sys BP (mmHg)
Diagnosis HbA1c	HbA1c (%)
Current Smoking	Current smoking status (0=Never, 1=Past smoker or 2=Current smoker of tobacco)
Current Chol	Cholesterol in mmol/l
Current HDL	HDL Cholesterol in mmol/l
Current Sys BP	Sys BP (mmHg)
Current HbA1c	HbA1c (%)
Pre-existing IHD	Number of years since pre-existing IHD
Pre-existing CHF	Number of years since pre-existing CHF
Pre-existing Amp	Number of years since pre-existing amputation
Pre-existing Blind	Number of years since pre-existing blindness
Pre-existing Renal	Number of years since pre-existing renal failure
Pre-existing Stroke	Number of years since pre-existing stroke
Pre-existing MI	Number of years since pre-existing MI
Discounting start year	

e.g.

001A,1,1,M,60,10,85,1.80,N,N,0,4.00,1.15,125,7.0,0,4.00,1.15,125,7.0,0,0,0,0,0,0,0
 002B,1,1,M,60,10,85,1.80,N,N,0,4.00,1.10,130,7.5,0,4.00,1.10,130,7.5,0,0,0,0,0,0,0
 003C,1,1,M,60,10,85,1.80,N,N,0,4.00,1.05,135,8.0,0,4.00,1.05,135,8.0,0,0,0,0,0,0,0

{name}_SmokingStatus.csv

This file contains the updated risk factors for Smoking status. It is only required if you select the ‘Use updated risk factor files’ option. The format is as follows:

ID	An identifier for the subject
Smoking: Year 1	smoking status (0=Never, 1=Past smoker or 2=Current smoker of tobacco)
...	
Smoking: Year 40	smoking status (0=Never, 1=Past smoker or 2=Current smoker of tobacco)

e.g.
 001A,1,,,2,,1,,,
 002B,,2,,2,,,,,2,,,
 003C,,

{name}_Cholesterol.csv

This file contains the updated risk factors for cholesterol. It is only required if you select the ‘Use updated risk factor files’ option. The format is as follows:

ID	An identifier for the subject
Cholesterol: Year 1	Cholesterol in mmol/l
...	
Cholesterol: Year 40	Cholesterol in mmol/l

e.g.
 001A,6.5,6.5,6.5,6.5,6.5,6.5,6.5,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
 002B,4.1,,,,,5.1,,,
 003C,,

{name}_HDL.csv

This file contains the updated risk factors for HDL cholesterol. It is only required if you select the ‘Use updated risk factor files’ option. The format is as follows:

ID	An identifier for the subject
HDL: Year 1	HDL in mmol/l
...	
HDL: Year 40	HDL in mmol/l

e.g.
 001A,0.9,0.9,0.9,0.9,0.9,0.9,0.9,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
 002B,1.1,,,,,1.1,,,
 003C,,

{name}_SysBP.csv

This file contains the updated risk factors for Systolic blood pressure. It is only required if you select the ‘Use updated risk factor files’ option. The format is as follows:

ID	An identifier for the subject
SysBP: Year 1	Sys BP (mmHg)
...	
SysBP: Year 40	Sys BP (mmHg)

e.g.
 001A,120,,,120,,,,120,,,
 002B,,130,,,154,,,
 003C,,

{name}_HbA1c.csv

This file contains the updated risk factors for HbA1c. It is only required if you select the ‘Use updated risk factor files’ option. The format is as follows:

ID	An identifier for the subject
HbA1c: Year 1	HbA1c (%)
...	
HbA1c: Year 40	HbA1c (%)

{name}_Bootstraps.csv

Bootstrap Number	
Life expectancy (All)	
Total QALE (All)	
Total cost of complications (All)	
Life expectancy (Group 1)	
Total QALE (Group 1)	
Total cost of complications (Group 1)	
Life expectancy (Group 2)	
Total QALE (Group 2)	
Total cost of complications (Group 2)	

e.g.

Bootstrap Number,Life expectancy,Total QALE,Total cost of complications
 1,5.527663982,4.272755081,5509.484561,9.134222203,7.100436072,5226.466521,1.921105761,1.445074089,
 5792.502601
 2,8.883901823,6.782036675,7071.075513,9.606008875,7.328607168,5532.870861,8.161794771,6.235466182,
 8609.280166
 3,7.938116905,6.077276854,6578.451473,7.383042576,5.715983362,4583.544646,8.493191234,6.438570345,
 8573.3583

{name}_IHD.csv

{name}_MI.csv

{name}_HeartFailure.csv

{name}_Stroke.csv

{name}_Amputation.csv

{name}_Blindness.csv

{name}_RenalFailure.csv

{name}_DiabDeath.csv

{name}_OtherDeath.csv

{name}_AllDeath.csv

Contain the cumulative event rates for each type of event. Each of these files has the following format:

ID	The identifier for the subject as provided in the <i>_Inputs</i> file
Event: Year 1	Event rate for year 1 (point estimate)
...	
Event: Year 40	Event rate for year 40 (point estimate)
Lower CI: Year 1	Event rate for year 1 (lower CI)
...	
Lower CI: Year 40	Event rate for year 40 (lower CI)
Upper CI: Year 1	Event rate for year 1 (upper CI)
...	
Upper CI: Year 40	Event rate for year 40 (upper CI)
Long term history: Year 1	Long term history rate for year 1 (point estimate)
...	
Long term history: Year 40	Long term history rate for year 40 (point estimate)
Long term history Lower CI: Year 1	Long term history rate for year 1 (lower CI)
...	
Long term history Lower CI: Year 40	Long term history rate for year 40 (lower CI)
Long term history Upper CI: Year 1	Long term history rate for year 1 (upper CI)
...	
Long term history Upper CI: Year 40	Long term history rate for year 40 (upper CI)

inputs sheet. For non-parametric columns the first row contains the number of values that match the first category value, the second row the second value etc.

These 3 rows are repeated for All subjects, Group 1 and Group 2

Subject characteristics rows

Group	Name of group
Count	Number of subjects in group
Ethnicity	Row 1 # White, row 2 # Afro-Caribbean and row 3 # Asian-Indian
Gender	Row 1 # Male and row 2 # Female
Age	Row 1 mean, Row 2 standard deviation, Row 3 number of values
Duration of diabetes	Row 1 mean, Row 2 standard deviation, Row 3 number of values
Weight	Row 1 mean, Row 2 standard deviation, Row 3 number of values
Height	Row 1 mean, Row 2 standard deviation, Row 3 number of values
Diagnosis Atrial Fib.	Row 1 # Yes, row 2 # No
Diagnosis PVD	Row 1 # Yes, row 2 # No
Diagnosis Smoking	Row 1 # Never, row 2 # Past smoker and row 3 # Current smoker of tobacco
Diagnosis Chol	Row 1 mean, Row 2 standard deviation, Row 3 number of values
Diagnosis HDL	Row 1 mean, Row 2 standard deviation, Row 3 number of values
Diagnosis Sys BP	Row 1 mean, Row 2 standard deviation, Row 3 number of values
Diagnosis HbA1c	Row 1 mean, Row 2 standard deviation, Row 3 number of values
Current Smoking	Row 1 # Never, row 2 # Past smoker and row 3 # Current smoker of tobacco
Current Chol	Row 1 mean, Row 2 standard deviation, Row 3 number of values
Current HDL	Row 1 mean, Row 2 standard deviation, Row 3 number of values
Current Sys BP	Row 1 mean, Row 2 standard deviation, Row 3 number of values
Current HbA1c	Row 1 mean, Row 2 standard deviation, Row 3 number of values
Pre-existing IHD	Row 1 mean, Row 2 standard deviation, Row 3 number of values
Pre-existing CHF	Row 1 mean, Row 2 standard deviation, Row 3 number of values
Pre-existing Amp	Row 1 mean, Row 2 standard deviation, Row 3 number of values
Pre-existing Blind	Row 1 mean, Row 2 standard deviation, Row 3 number of values
Pre-existing Renal	Row 1 mean, Row 2 standard deviation, Row 3 number of values
Pre-existing Stroke	Row 1 mean, Row 2 standard deviation, Row 3 number of values
Pre-existing MI	Row 1 mean, Row 2 standard deviation, Row 3 number of values
Discounting start year	Row 1 mean, Row 2 standard deviation, Row 3 number of values

e.g.

Group,Count,Ethnicity (1/2/3),Gender (M/F),Age (y) (Mean/SD/N),Duration of diabetes (y) (Mean/SD/N),Weight (kg) (Mean/SD/N),Height (m) (Mean/SD/N),Atrial Fib. (Y/N),PVD (Y/N),Smoking (0/1/2),Chol (mmol/l) (Mean/SD/N),HDL (mmol/l) (Mean/SD/N),Sys BP (mmHg) (Mean/SD/N),HbA1c (%) (Mean/SD/N),Smoking (0/1/2),Chol (mmol/l) (Mean/SD/N),HDL (mmol/l) (Mean/SD/N),Sys BP (mmHg) (Mean/SD/N),HbA1c (%) (Mean/SD/N),IHD (Mean/SD/N),CHF (Mean/SD/N),Amp (Mean/SD/N),Blind (Mean/SD/N),Renal (Mean/SD/N),Stroke (Mean/SD/N),MI (Mean/SD/N),Discounting offset (y) (Mean/SD/N)
 All,8,8,4,60.0,10.0,82.5,1.7,0.0,8,4.0,1.1,132.5,7.8,8,4.0,1.1,132.5,7.8,0.0,0.0,0.0,0.0,0.0,0.0,0.0,0.0
 ,,0,4,0.0,0.0,4.9,0.1,8,8,0.0,0.0,1,11.0,1.1,0.0,0.0,1,11.0,1.1,0.0,0.0,0.0,0.0,0.0,0.0,0.0
 ,,0,,8,8,8,,0,8,8,8,0,8,8,8,8,8,8,8,8,8,8,8

Smoking status rows

Contains three rows for each group, the first row contains the number of values that match the first category value, the second row the second value etc

Label	Row 1 0s, Row 2 1s, Row 3 2s
Year 1	Row 1 # Never, Row 2 # Past smoker, Row 3 # Current smoker of tobacco
...	
Year 40	Row 1 # Never, Row 2 # Past smoker, Row 3 # Current smoker of tobacco

e.g.

Id,Year 1,Year 2,Year 3,Year 4,Year 5,Year 6,Year 7,Year 8,Year 9,Year 10,Year 11,Year 12,Year 13,Year 14,Year 15,Year 16,Year 17,Year 18,Year 19,Year 20,Year 21,Year 22,Year 23,Year 24,Year 25,Year 26,Year 27,Year 28,Year 29,Year 30,Year 31,Year 32,Year 33,Year 34,Year 35,Year 36,Year 37,Year 38,Year 39,Year 40

Label	Row 1 Mean, Row 2 SD, Row 3 N
Year 1	Row 1 mean, Row 2 standard deviation, Row 3 number of values
...	
Year 40	Row 1 mean, Row 2 standard deviation, Row 3 number of values

e.g.
 Id,Year 1,Year 2,Year 3,Year 4,Year 5,Year 6,Year 7,Year 8,Year 9,Year 10,Year 11,Year 12,Year 13,Year 14,Year 15,Year 16,Year 17,Year 18,Year 19,Year 20,Year 21,Year 22,Year 23,Year 24,Year 25,Year 26,Year 27,Year 28,Year 29,Year 30,Year 31,Year 32,Year 33,Year 34,Year 35,Year 36,Year 37,Year 38,Year 39,Year 40
 Mean,120.0,,130.0,,120.0,,154.0,,,120.0,,,,,,,,,,,,,,,,,,,,,,,,,
 SD,,,,,,,,,,,,,,,,,,,,,,,,,
 N,1,0,1,0,1,0,1,0

{name}_EstimatedSmokingStatus.csv
 Smoking status values as estimated by the UKPDS Outcomes Model. If updated risk factors are provided they are reproduced in this sheet.

ID	The identifier for the subject as provided in the <code>_Inputs</code> file
Year 1	Estimated value for year 1, or updated risk factor value if provided
...	
Year 40	Estimated value for year 40, or updated risk factor value if provided

{name}_EstimatedLipidRatio.csv
 Lipid values as estimated by the UKPDS Outcomes Model. Lipid values provided by the model are a ratio of Total Cholesterol to HDL. If updated risk factors for Cholesterol and HDL are provided the ratio is reproduced in this sheet.

ID	The identifier for the subject as provided in the <code>_Inputs</code> file
Year 1	Estimated value for year 1, or updated risk factor value if provided
...	
Year 40	Estimated value for year 40, or updated risk factor value if provided

{name}_EstimatedSysBP.csv
 Systolic blood pressure values as estimated by the UKPDS Outcomes Model. If updated risk factors are provided they are reproduced in this sheet.

ID	The identifier for the subject as provided in the <code>_Inputs</code> file
Year 1	Estimated value for year 1, or updated risk factor value if provided
...	
Year 40	Estimated value for year 40, or updated risk factor value if provided

{name}_EstimatedHbA1c.csv
 HbA1c values as estimated by the UKPDS Outcomes Model. If updated risk factors are provided they are reproduced in this sheet.

ID	The identifier for the subject as provided in the <code>_Inputs</code> file
Year 1	Estimated value for year 1, or updated risk factor value if provided
...	
Year 40	Estimated value for year 40, or updated risk factor value if provided

Automating runs of the model

As of version 1.2.1 of the Standalone Implementation of the UKPDS Outcomes Model it is possible to start a simulation of the model without user intervention. This feature, called batch mode, allows the model to be run from the command line or even from other suitable applications.

To run the model in batch mode you need to issue the following command:

```
"UKPDS Outcomes Model.exe" /run <name of .outcomes file>
```

For example:

```
"UKPDS Outcomes Model.exe" /run c:\Sample.outcomes
```

This would start the Standalone Implementation of the software, load the specified parameter set file and start the simulation. Once the simulation is complete the program will quit leaving the output files in the same directory as the .outcomes file.

In order to use this facility the application wishing to start the simulation must be able to issue commands to the operating system. For example applications written in Visual Basic are able to do this using the Shell function. From SAS you can use the X statement, see the 'Running DOS or Windows Commands from within SAS' section of 'SAS Companion for the Microsoft Windows Environment'.

Please note that the full path to the .outcomes file must be specified in order for the system to work. That is you cannot simply use samples.outcomes or ..\samples.outcomes. If the folder containing the UKPDS Outcomes Model software has not been placed on the system path you will need to use the full path to the executable in order for it to work correctly.