

Multiscale Immune System SImulator for the Onset of Type 2 Diabetes integrating genetic, metabolic and nutritional data

Work Package 8

**Deliverable 8.7** 

**Exploitation Report** 





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	This is the exploitation report deliverable following the
	intermediate exploitation report D8.4. Here we account for
	the updated integration with the T2D-MISSION model
	results, and also with the state of the mobile application as
Executive Summary	the main means of exploitation.
	The document also provides an assessment of user
	for a decimient allocipion account of a contract of a cont
	Teedback in terms of statistical measure of user answers to
	the survey created for the purpose and described in D8.6.
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# 1 Premise

The original plan for the exploitation of the project MISSION-T2D results has undergone modifications during the last months of the project. In particular, some delay in the release of the mobile app has somehow narrowed the time at our disposal to collect the users' feedback that we planned to discuss in this deliverable. The reasons are explained below.

This unfortunate event however has not prevented to conclude all technical work, which indeed has been concluded as planned (the MISSION-T2D feature that calculates the risk of T2D from user input has been integrated in the VitaDock+ Medisana app). The 3 months delay in the release of the VitaDock+ in mobile software stores (eventually in late May 2016) has limited the number of users' feedback to less than fifty. However, since the review meeting will take place at the end of June, there is still a whole month ahead for data collection and therefore statistically meaningful information will be available for that event.

### 1.1 Reasons for the delay

The MISSION-T2D section embedded into Medisana's VitaDock+ mobile application was scheduled to be released within the timeframe of the project, allowing partner MED to gather real customer feedback during the extension period granted. However, before this took place, several events interfered, preventing Medisana from releasing the update in its original form.

At first, last minute **management decisions** concerning the wording of parts of the MISSION-T2D section (it was feared that the wording may have been too direct, irritating the user/customer more than being informative towards the risk of diabetes development) forced the release to be postponed, followed by a strategic decision to prioritize the release of a design overhaul of the whole mobile application's interface forced the release date further back.

Due to a following **issue with one of Medisana's hardware products** (i.e., the Activity Tracker) supported by the VitaDock+ application, the production lines at the supplier's factory were halted and the development schedule on both sections needed to be adapted. Medisana's mobile application developers were required to put in unscheduled work, to alter the behavior of the VitaDock+ application to overcome the tracker's issues. The extra work required pushed the deadline further back towards mid-April (precisely 18.04.2016).

A pending **sales campaign** of a major German discounter (Penny) of a large number of two Medisana's hardware products supported by the VitaDock+ application (bodyweight scale, blood pressure meter), raised concerns within Medisana's marketing and sales departments. They pointed out that the update and potential connected problems may result in a larger number of returned items by unhappy customers, rendering the campaign a financial failure. This caused the release date to be pushed further (May 2nd).

Again, due to **decisions by management**, a two-step release was then settled, as it was considered risky to confront the existing user base with a new update to the VitaDock+ application, altering the complete user interface and also the way existing customers are accustomed to using the application, while at the same time introducing the MISSION-T2D contents.

#### 1.2 Resolution

Luckily, such delay has not prevented the MISSION-T2D consortium to reach the PM38 objective, which was the reason for asking the two-months extension. In fact at the time of writing of the present second version of the dissemination report, we had the time to collect **some** user-feedbacks about usage and acceptance of the MISSION-T2D element in the VitaDock+ app (as reported at in the last section of this document). This thanks to the fact that by the end of May, VitaDock+ has eventually been released. Therefore, it is expected that by the time the review meeting will take place at the end of June, the consortium will be able to offer a fairly good account of users' feedback data.

#### 2 Introduction

Over the duration of the MISSION-T2D project, the project partners identified and/or developed several models describing different areas covering aspects of the human physiology related to the metabolic instabilities leading to type 2 diabetes. These models include one describing the immune activation and inflammation, integrating and extending an agent-based model of the immune system (CNR, M1), a model for metabolism, including multiple tissue compartments (TNO, M2), a model for insulin resistance or beta-cells' efficiency (UniCAM, M3) and a model to account for the effects of physical activity on the inflammatory state of the individual as well as its energy intake-expenditure balance (USFD, UniRM, M4) with the purpose of providing a diagnostic tool to estimate the risk of developing Type 2 Diabetes and predict its

progression over time.

#### 2.1 Use of MISSION-T2D findings in mobile applications

These models and the extensive simulations' loads of these models exceed the capabilities of modern day smartphones by far. On the other hand, the resulting data is of such detail that it is not feasible to be displayed on the limited space for visualization of today's mobile devices. A fairly average personal computing device (e.g., PC) currently requires up to about a week to compute the data produced by such an extensive simulation for a time period of one year at a resolution of one minute. As a consequence the computations required to determine an individual's risk of developing Type 2 Diabetes cannot be run on a mobile device at present time. The computational time required to run a single simulation corresponding to a query for forecast issued by the user is "to date" very demanding, notwithstanding the effort of partner CNR to speed-up computation. Even if the six-days time required will be reduced by an order of magnitude, it is unrealistic to hope for a real-time execution of the model on a limited capacity hardware as a mobile device. This was already foreseen at the beginning of the project and a solution to this problem has been long identified as discussed below.

With mobile phones and especially smartphones, devices with advanced operating systems, capable of internet access and running third party applications and interfaces for internal and external sensors, having spread into almost every household in society, they are an ideal tool for self-monitoring health and lifestyle aspects, and, in particular, for the findings of the project MISSION-T2D.

The solution to bypass the computational capacity deficit in current day smartphones and tablets and to work around the extended simulation time even on much faster and more capable platforms, is to run and record an extensive amount of simulations on appropriate hardware, like university computing centers or cloud computing facilities, to create a vast number of results for a wide spectrum of physiological parameters. The resulting data is then broken down into one or multiple lookup tables, which summarize results for specific configurations (or set of configurations clumped together) and subsequently enabling estimations to be made on mobile devices. Partner CNR in charge for the development of the final simulation engine (WP6) will be conducting the required extensive scan of the parameter space and clusterize the results on the basis of carefully chosen identifiable outputs. The resulting parameter & initial condition / forecasted values will constitute the lookup tables that will eventually be imported into the mobile app and consulted upon the user request.

# 3 The MISSION-T2D Integrated Model

The development of the integrated model is due to partner CNR as described in deliverable D6.2. To the purpose of the present exploitation report we now give a brief overview of the main idea and functions. The following figure evidences the kind of input/outputs taken/given by the MISSION-T2D integrated model. The input includes a parameterised version of the physical activity pattern of the user, e.g., total number of hours of PA per week and the average intensity or a more detailed weekly schedule or - if a measurement device is available - the weekly pattern of activity as measured which is then assumed to repeat unchanged for each week. Another input is the nutritional habit of the user on a daily or weekly basis. The cumulative daily meal will be broken down in the macronutrients, meaning, proteins, fat and carbohydrates. A finer grain classification of nutrients is actually used at this stage as the model developed by UniBO in WP2 (described in deliverable D2.4 and also in D6.2) accounts for these to determine the level of butyrate and propionate directly influencing the tendency of the immune system to drift toward the inflammatory state.

Other general parameters characterising the user include the age, gender, weight, etc. All these constitute the boundary condition of the model execution, which will then forecast the metaflammation state at the "forecasting horizon time T". The simulation runs and returns the detailed dynamics of dozens of variables. These are ultimately used to calculate a unique value identifying the risk of T2D at time T (as indicated in the figure). The "risk of T2D" will therefore be a complex function accounting for the level of insulin resistance (e.g., efficiency of beta-cells) and the level of inflammatory cytokines and pro-inflammatory cell counts.





Figure 1: The MISSION-T2D Integrated Model

As mentioned, the mobile app will not run the simulation for computational reasons, therefore we will precompute a number (large) of input/output relationships, and fill a multidimensional table that will represent a sampling of the function realised by the model. This table will then be plugged into the mobile app.

### 4 Specification of the MISSION-T2D mobile application

The mobile application as MISSION-T2D's primary means of exploitation is specified to provide users with a powerful tool to self-monitor health and lifestyle aspects and employ these to receive an estimate on the risk of developing Type 2 Diabetes.

#### 4.1 User Profile

By querying the current user for some initial personal information, such as the birthdate, the body height and initial weight, as well as the user's gender upon first start of the application, the mobile application is able to create an individual user profile. Additional information, specifically requested for the purpose of determining the Type 2 Diabetes risk (such as the Enterotype levels, Butyrate, Pyruvate, if available, or an estimation of proportion of macronutrients in her/his diet; the level of physical activity exercise per week) but also data to specify individual goals and target range values for measurement results can be entered in corresponding sections in the application's settings.





Figure 2: Personal Data to be used in MISSION-T2D feature in the Medisana mobile application

Already from this information, assuming average levels for all measurable inputs to be covered by the mobile application, the software should be able to derive a basic estimate of the risk of developing Type 2 Diabetes in the context of the current user.

#### 4.2 External Sensors

With the increasing miniaturisation of digital sensors more and more mobile devices have been equipped with these sensors and they're applied to all kinds of scenarios. First mobile phones received sensors such as gyroscopes, magnetometers, accelerometers and barometers, only to name a few.

Then, as of late, many more sensor equipped devices, primarily from the sports and lifestyle sector have flooded the markets. These devices, mainly activity meters and heart rate monitors, some including GPS localization services, are commonly referred to as 'wearables' and can be employed to measure a user's physical activity, which is one of many important factors in determining the user's health. The sector of Wearables is thought to grow exponentially over the coming years, a trend that is underlined for example by numerous activity trackers and the rise of "smartwatches", which are usually equipped with multiple sensors.

In addition a broad range of medical sensors, such as glucose meters, blood pressure meters, pulse oximeters and others featuring wired or wireless data transfer mechanisms have become widely available. The combination of smartphones, external sensors and transmission through short-range wireless technology such as Near Field Communication (NFC), Bluetooth or WiFi open up a broad range of applications and come in handy for MISSION-T2D in particular.

#### 4.3 Self-monitoring in MISSION-T2D application

In order to improve the individual estimation of the Type 2 Diabetes risk the MISSION-T2D mobile application establishes a user journal of health and lifestyle parameters containing automatically measured or manually entered values. Within the duration of the project the inclusion of a minimum of two external sensors is anticipated to support users in self-monitoring and reduce uncertainties in the estimate of Type 2 Diabetes risk. Additional means of entering data manually will be supplied for users not making use of compatible sensor devices and where such sensors are not available.

#### 4.3.1 Measuring Physical Activity

As a means of measuring physical activity a wrist or pocket worn pedometer is employed to provide an account of steps taken by the user of up to 96 intervals of 15 minutes each. Additionally the data contains the amount of actively burned calories and an estimation of crossed distance within the interval. The sensor supports wireless transmission of data through Bluetooth Low Energy technology and is compatible with most modern Bluetooth capable mobile devices. The sensor can store data of up to 15 days before the local memory is exceeded and old data is being overwritten.



Figure 3: Wrist worn activity meters ViFit Connect, Touch, MX3

Also capable of measuring movements during sleep, the pedometer may, at a later point, be used to determine sleep quality data, if required.

#### 4.3.2 Estimating Physical Activity

The application also permits the user to manually specify levels of activity on a per day basis, asking the user to describe his performance in terms of low, medium or high levels of activity, which, under consideration of the personal step goal specified by the user, will be used to estimate an absolute daily total amount of steps for the specified day.

While not exact and subject to misinterpretation by the user, a very basic account for the user's physical activity is favourable over not having any such data, of course.

Resembling the design of the weekly overview graph in the mobile application, in the manual entry section the user can quickly and easily provide an estimate without having to refer to complex mechanisms to describe individual sessions of physical activity. Such more advanced methods may be supplied at a later stage, should it become obvious that a greater level of detail in regards to individual sessions is required. Initial research into this area did not hint in this direction and make it likely that a daily performance summary may be sufficient for computing an estimate.



Figure 4: Weekly Overview (left) and manually entering physical activity (right)

#### 4.3.3 Measuring Blood Glucose

In order to measure the blood glucose levels a small teststrip based sensor is used. The sensor determines the concentration of glucose through enzymes on the teststrip, which is being inserted into the sensor device prior to the application of a small amount of blood. The device has a large display and a local memory has a capacity for up to 480 measurements before old results are being overwritten.



Figure 5: Teststrip based glucose meter MediTouch 2 Connect

The device also enables the user to determine whether a measurement was performed prior or following a meal, as the time of measurement in respect to food intake can influence the measurement result.

#### 4.3.4 Manually entering glucose data

As an optional means of adding glucose level results to the journal of health and lifestyle parameters, an interface is being provided through which the user can enter the results of glucose measurement and provide the date and time of such a measurement.

Additionally, it is intended to provide means of entering additional data determined through more sophisticated means of measurement, e.g., through a GP, covering inflammatory markers such as IL-6.



Figure 6: Entering glucose data manually in MISSION-T2D mobile application

#### 4.3.5 Monitoring nutritional habits

Another major factor in personal health, nutritional habits play an important role in the models employed by MISSION-T2D. Currently no sensors devices measuring the intake of (macronutrients) carbohydrates, proteins and fat are available, thus the mobile application's interface will provide the user with means of entering estimates of the percentage of each in relation to the weekly total meals.

#### 4.3.6 Additional measurement data and sensor devices

While initially only two sensors will be included, many more such sensors are available and may be feasible to be included in the application. Additionally, with the use of the VitaDock Online platform, there exists the option to access measurement data gathered through the platform itself without having to implement the routines for data synchronization with an external measurement device in the MISSION-T2D software application itself. This, given sufficient time and resources, may allow to extend the mobile application to also include long term observations of a user's body weight, heart rate and blood pressure, for example.



Figure 7: Bodyweight scale BS 440

# 4.4 Estimating the risk of Type 2 Diabetes

The goal of the journal, apart from providing the user with the opportunity to collect and review a history of health and lifestyle parameters, is to use these parameters as input for the estimate of the risk of developing Type 2 Diabetes through the lookup tables derived from the simulations. The additional input generated through the supported sensor devices and manual entries help reducing uncertainties in the estimation.



	MISSION-T2D	
STAT	ISTICALEVALUAT Results	ION
Diabetes Ris	k	
5	6.5	0
5	7.5	Tendenz
Body Mass I	ndex	
<b>2</b> 25.3 BM	9.5	0
15 BMI	50 BM	Tendenz
Inflammatio	n	
0	8.8	
0	20	Tendenz
	ОК	
		المراجعين المراجع

Figure 8: Type 2 Diabetes risk estimation

Estimations are provided to the user in percentage values, representing the likelihood of developing Type 2 Diabetes over the given period of time.

### 5 Limitations

Despite the successful use of lookup tables in order to circumvent the limitations in computing power when it comes to the full-fledged simulations of physiological processes over a long time period, mobile applications face a range of other limitations imposing restrictions on the use of these devices on self-monitoring and self-diagnosis.

### 5.1 Capacity limitations

The mobile application itself only maintains records of the last 30 days, a step that ensures faster loading of the application and reduced data requirements when synchronizing with the VitaDock Online platform, as well, in general, a lesser risk of exposure, in case the device running the mobile application is subject to unauthorized access.

Already during the MISSION-T2D lifetime and the realization of the mobile application, it may become a requirement to include a mobile database engine to support more performant data management.

#### 5.2 Risk factors

One risk standing out aside from normal considerations, such as using the software application in unintended ways or misinterpreting the application's output, is that any potential error made during the programming or even the preceding simulations and generation of the used lookup tables requires an update to the application, which also must be deployed on the affected devices.

While adoption rates of application updates are in good in general, it needs to be considered that the error analysis, planning, realization and verification of a bugfix as well as additional requirements for approval and distribution through the corresponding channels, Apple's App Store and the Google Play Store, delay the arrival of results at the end user and as such extend the time period during which the user is likely to be affected by the errors.





Also, facing the fact that giving an estimate on the development of type 2 diabetes effectively makes the MISSION-T2D mobile application a tool not only for self monitoring but diagnosis in a limited sense, it is desirable that not just the majority of users have access to the latest versions, but all users.

# 6 Further exploitation

Due to the focus on research and innovation, as well as the limited timeframe of the project, the MISSION-T2D mobile application is only the initial means of exploitation. In discussions among partners a number of ideas have been brought to the table, which may be realized by the end or after the completion of the project.

### 6.1 Integration in existing client solutions

Figure 9: Update adoption of a mobile application in March 2015 by partner MED, showing 13% of users running outdated software versions, some not having updated for over a year.



Already near the end of the MISSION-T2D lifetime or shortly thereafter, the integration of the project's findings into existing, commercially available products can be considered likely. Partner MED does provide multiple mobile applications which may benefit greatly from the features similar to those implemented into the MISSION-T2D mobile application and can further improve the input parameters by including data from more sensor devices, too.

Such an integration, potentially also at first delivered as an optional, manually activated feature, would serve to carry the results of the project to audiences of several ten to hundred-thousand users, based upon the choice of the application.

### 6.2 Integration in existing online platforms

Aside from its mobile applications partner MED also maintains a commercially available web-based platform with more than 100.000 registered users at the end of 2014. This platform aggregated over 4 million individual measurement results gathered through over a dozen available sensor devices and multiple mobile and desktop applications and serves both as a means for data backup as well as device to device synchronization of measurements and user profiles.



Figure 10: Weight section of VitaDock Online platform.

A publicly available API allows for reading and writing data, with a complex authentication system restricting access to only those applications approved by partner MED and only to those accounts and stored results where the explicit user's consent



was given.



Figure 11: VitaDock API Access.

One distinguishing aspect of integrating the MISSION-T2D findings into this or a comparable platform is the ability to not merely calculate an estimate for an individual person based upon the complete historical record of individual measurement results, but to also provide comparisons in regards to greater groups of users.



Percentage of VDO users with BMI of ..





Figure 13: Weekly averages of active ViFit users

In such a scenario an individual user would be enabled to compare his own estimation of the risk of developing type 2 diabetes against that of one of multiple virtual groups, say other VitaDock+ users of the same age, gender or BMI, further taking into account the measured health and lifestyle parameters of members of these groups.

#### 6.3 Server based approach

The MISSION-T2D approach of implementing the lookup tables resulting from the extensive simulations inside a mobile device application may at some point need to be replaced by a server-based implementation, which, while not reducing the risk of errors in the implementation, dramatically reduces the response time to any such error and guarantees a 100% adoption rate of the affected areas, as only a single central instance of the approach requires maintenance in this special case.

Despite the greater computational capacity of server technology, it is however still not likely to perform a complete simulation for an individual user profile, but instead the concept of lookup tables may be exploited in increased resolution.

#### 6.3.1 Exploitation as a service

Another positive aspect of a central interface accessible through mobile - or other - applications is that the coverage can be easily extended to inclusion in web-based services, which may be exploited internally by the project partners or even provided as

a publicly accessible service, as far as offering means of integration into third party applications, by far extending the initial intended use. This is likely to lead to inclusion in a greater number of projects and platforms, which may combine the results with other, similar estimation technologies for other areas of human physiology.

Partner MED already participates with 3rd parties, such as health insurers, in separate programs focused on coaching diabetes patients, as well as customers without imminent medical conditions, to promote the positive effects of physical activity and a healthy diet on personal health and mental wellbeing. These, as well as related programs are ideal to feature findings of the project.

# 7 Summary of the User Questionnaire

A preliminary summary of the users' responses regarding the MISSION-T2D feature in the mobile application already reveals a significant interest in the effects of a healthy diet and physical activity on the risk of developing Type 2 Diabetes.



# 7.1 Gender Distribution

Figure 14: Gender distribution of completed Questionnaires

At the early stages after the release of the mobile application, the distribution of male and female participants in the questionnaire is all but even.

# 7.2 Age Distribution



The age distribution shows a peak among users between 30 and 60 years. This underlines that the mobile application and supported measurement devices are not merely tools used by 'early-adopters' of a 'digital generation', but they are also well accepted among older users.

7.3 Question 1 - How curious are you about your personal risk of developing Type 2 Diabetes?



Replies to the first question express a fair interest in the individual risk of developing Type 2 Diabetes.



7.4 Question 2 - How important are physical activity and a healthy diet for you?

Figure 17: Diet and activity are of great importance

Participants of the online survey regard the driving factors diet and activity as very important.

7.5 Question 3 - How interested are you in a more detailed forecast (e.g. daily values) of BMI, Glucose and Inflammation?



Due to reasons of computational capacity, results of the simulation were limited to a weekly resolution. In future implementations, participants would like to view them in a higher resolution, e.g., down to changes from day to day.

7.6 Question 4 - How important is it for you to export the data to other applications (CSV, Excel, PDF, etc.)?



There exists a fair desire to export data for use in other applications among participants of the survey, but in general, it doesn't appear to be a major concern.



# 7.7 Question 5 - Do you consider it necessary to receive a forecast for e.g. 1 year, 2 years or more?

Figure 20: Some users wish for a longer simulation period

Participants are expressing the desire to extend the simulation period beyond the current limit of 6 months = 24 weeks.

7.8 Question 6 - Are you curious to learn how increased activity and/or a healthy diet affects your personal risk of developing Type 2 Diabetes?



Future releases of the mobile application would do well on detailing the impact of (healthy) diets and physical activity on the risk of developing Type 2 Diabetes.

7.9 Question 7 - Would you like to see the impact of increased activity and/or a healthy diet in the simulation data?





Not surprisingly, resulting also from Question 6, there exists a desire to view the direct impact of increased activity and a healthier diet – in other words 'lifestyle changes' – in the risk forecast.





Figure 23: Participants seek more data beyond pre-computed results

Resulting from the limited set of input parameters (e.g., options 'little – average' & 'high' for average fat intake) that adjustable by participants, the wish to customize these parameters is understandable. However, due to the constraints in computational capacity, it would require to put databases of pre-computed results aside and focus on feeding the user parameters directly into the simulation engine. This aspect and take home message that the consortium is getting from it is described in the deliverable 8.6.

# 7.11 Question 9 - Do your results affect your decision regarding a balanced and healthy lifestyle and diet?



Maybe a little surprising, participants in the survey expressed that the results of a risk forecast of the development of Type 2 Diabetes have a significant impact on health and lifestyle decisions. Combining the results with advice & coaching regarding diet and physical activity, as well as visualizing the positive impact of such lifestyle changes upon the simulation results yields huge potential.

7.12 Question 10 - Would you consider paying a small fee for a more detailed interpretation of your data by a general practitioner or other medical staff?



#### Figure 25: Participants are not very willing to pay for such a service

Also not surprisingly, participants expressed a fair opposition against paying a small fee for services similar to the MISSION-T2D feature in the mobile application. However, further research may reveal a generally acceptable service fee or other business models.

# 7.13 Question 11 - Would you like to see more features like this for other medical conditions in mobile applications?



Figure 26: Participants show medium interest in covering other areas

The majority of users are also in favour of expanding the mobile application to include similar features, hinting as future opportunities aiming at areas such as blood pressure, heart conditions, etc. which may also show strong relations to factors such as dietary habits, physical activity, obesity.



# 8 Summary

All in all, the users' feedback collected through the online questionnaire has evidenced a discrete interest on the features brought on by the MISSION-T2D project. Users have shown to be sensible to means of improving their life style and willingness to follow advices given by self monitoring devices equipped with software enabling mathematical and statistical predictions on the basis of the current physical/health status and predicted behaviour over a certain time window. Interestingly the users would like to have this forecast to extend to the future as much as possible. They are extremely interested in having user-customised models for which are willing to pay a small fee.

Further analysis of this kind will be available in the following week with the expected increase of user participation allowing more extended statistics at our disposal.

# 9 Outlook

As the primary path of exploitation, partner MED seeks to extend the mobile application further, supporting additional sensor devices and adding more features.

The post-MISSION-T2D roadmap (though not strictly related to the project outcome itself, it is worth mentioning them here) for the mobile application contains several steps towards an improved overall user experience. One of these improvements focuses on increasing the stability and speed of the Bluetooth synchronization with sensor devices.

Additional measures will introduce visual comparisons of measured parameters over extended periods of time, revealing potential correlations in a user's data, e.g., such as effects of phases of increased physical activity on the development of blood pressure or blood glucose measurements.

Furthermore partner MED intends to introduce features to increase the users' motivation to regularly record their vital data, aiming both at competitions between users as well as rewarding users for reaching certain goals.

Hand in hand with these developments on the mobile application side go modifications on the VitaDock Online platform.

From an economic point of view, partner MED is intending to extend its business further towards Asia and North America in cooperation with partner companies with already established businesses there.





Figure 27: Development of Support Requests since 2013

If successful, the increase in its user base will introduce numerous new challenges, e.g., multi-language customer support, rapidly increasing demand for customer demand, distributed data centres and national regulations towards data security and privacy.