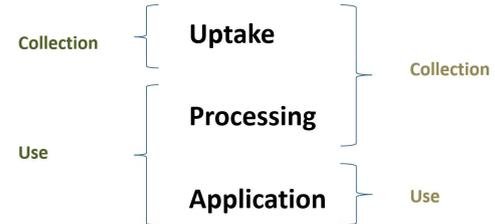


Data & Result Governance

Iterata Health Platform supports

- the Data Uptake – Processing and Application Process
- the Result Governance Level 1-4

Result Governance																
<p>Introduction</p> <p>To keep track over a large amount of data is often difficult. Intelligent algorithms which are trained in advance, should be a technical support next to the human thinking and decision-making process.</p> <p>It is one of our main principles to use the currently available technological features to support humans in their daily life. This should facilitate the whole process and minimize errors. Besides, it also saves a lot of time.</p> <p>Another approach of us is it to handle sensitive data safely and within a governance system. This is like an entry checkpoint, where a decision is made based on the authorization level of the user, which data is available to them and which not. This means, that the data gets categorized in advance, to identify different safety levels.</p>	<p>US → do not regulate collection, regulate use</p> <p>EU → need to know and contextual integrity</p> <div style="text-align: center;">  </div>															
<p>Data and Result Governance Level 1-4</p> <p>Level 1: availability of a patient set. No further information about the individuals, only if there are patients who meet the criteria (yes/no).</p> <p>Level 2: number of individuals who meet the criteria, number of groups. Still without any further information which describe the individuals in more detail (number of individuals).</p> <p>Level 3: anonymized data set, without names, but age and gender possible (number of individuals and anonymized information about them).</p> <p>Level 4: complete data set including all describing features of an individual (individuals including all personal information)</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 20%;"></th> <th style="width: 50%; text-align: center;">Possible Question</th> <th style="width: 30%; text-align: center;">Result, Feedback</th> </tr> </thead> <tbody> <tr> <td style="background-color: #e0e0e0; padding: 10px;"> <p>Level 1 </p> <p>Availability of Patient Set (Sample)</p> </td> <td style="padding: 10px;"> Do we have any patients with e.g. <ul style="list-style-type: none"> • Steven Johnson, Lyell Syndrom? • Medications MTX and RA? </td> <td style="padding: 10px;"> <ul style="list-style-type: none"> • <i>yes or no</i> </td> </tr> <tr> <td style="background-color: #e0e0e0; padding: 10px;"> <p>Level 2 </p> <p># Number of Patients, Groups</p> </td> <td style="padding: 10px;"> Is there a significant (critical) sample size, e.g. <ul style="list-style-type: none"> • How many patients have lab values for Troponin, BNP and etc.? </td> <td style="padding: 10px;"> <ul style="list-style-type: none"> • <i>number of patients</i> </td> </tr> <tr> <td style="background-color: #e0e0e0; padding: 10px;"> <p>Level 3 </p> <p>Question Focused Dataset (QFD)</p> </td> <td style="padding: 10px;"> Anonymized combination of a set of multi variables (study profiles, cohorts) filtered and aggregated <ul style="list-style-type: none"> • Full complete research QFD e.g. demographical, age, gender distribution </td> <td style="padding: 10px;"> <ul style="list-style-type: none"> • <i>number of patients based on QFD</i> </td> </tr> <tr> <td style="background-color: #ffff00; padding: 10px;"> <p>Level 4 </p> <p>Complete QFD for research study, agreed through patient * patient consent is relevant</p> </td> <td style="padding: 10px;"> <ul style="list-style-type: none"> • Study monitoring • Studies on medication interaction • Intervention studies • Patient support studies • </td> <td style="padding: 10px;"> <ul style="list-style-type: none"> • <i>patients based on QFD validated</i> </td> </tr> </tbody> </table> <p>Level 1-3 are mainly used for research, level 4 for clinical use. Depending on the function of the individual using the data, an access level is determined. Especially level 4 needs to be authorized for clinical context and access in terms of validation of the sensitive data.</p>			Possible Question	Result, Feedback	<p>Level 1 </p> <p>Availability of Patient Set (Sample)</p>	Do we have any patients with e.g. <ul style="list-style-type: none"> • Steven Johnson, Lyell Syndrom? • Medications MTX and RA? 	<ul style="list-style-type: none"> • <i>yes or no</i> 	<p>Level 2 </p> <p># Number of Patients, Groups</p>	Is there a significant (critical) sample size, e.g. <ul style="list-style-type: none"> • How many patients have lab values for Troponin, BNP and etc.? 	<ul style="list-style-type: none"> • <i>number of patients</i> 	<p>Level 3 </p> <p>Question Focused Dataset (QFD)</p>	Anonymized combination of a set of multi variables (study profiles, cohorts) filtered and aggregated <ul style="list-style-type: none"> • Full complete research QFD e.g. demographical, age, gender distribution 	<ul style="list-style-type: none"> • <i>number of patients based on QFD</i> 	<p>Level 4 </p> <p>Complete QFD for research study, agreed through patient * patient consent is relevant</p>	<ul style="list-style-type: none"> • Study monitoring • Studies on medication interaction • Intervention studies • Patient support studies • 	<ul style="list-style-type: none"> • <i>patients based on QFD validated</i>
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Please do not hesitate to contact us

Sincerely yours, Iterata Team

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