

App-Synopsis for Health-Apps and Medical-Apps nach Albrecht UV, Pramann O, von Jan U. "Synopsis for Health-Apps - Transparency for Trust and Decision Making" (2013).

<b>Item Category</b>	<b>Checklist Item</b>	<b>Sub Items</b>
1. Imprint	1.1 Meta Data	<ol style="list-style-type: none"> <li>1. Operating system</li> <li>2. Version number</li> <li>3. Web link (project pages and link to the app store)</li> <li>4. Category: Commercial project, non-commercial project, other</li> <li>5. Category: public access via an app store, only available to a restricted number of users/experts (in-house), other (please specify)</li> </ol>
	1.2 Developer/Distributor	<ol style="list-style-type: none"> <li>1. Information about the manufacturer/developer               <ol style="list-style-type: none"> <li>1.1. Name, address, web page, contact person(s), email address, phone and fax number</li> </ol> </li> <li>2. Information about the distributor               <ol style="list-style-type: none"> <li>2.1. Name, address, web page, contact person(s), email address, phone and fax number</li> </ol> </li> </ol>
	1.3 Sponsoring/Advertising	<ol style="list-style-type: none"> <li>1. Information about the funding used for developing the app               <ol style="list-style-type: none"> <li>1.1. Category: sponsoring, advertisements, other</li> </ol> </li> </ol>
2. Rationale	2.1 Category	<ol style="list-style-type: none"> <li>1. Category: medical product or not, if yes: which class; has the app been certified voluntarily (by whom?), uncertified app</li> </ol>
	2.2 User group	<p>For each user group:</p> <ol style="list-style-type: none"> <li>1. Specific disease / condition (or as an alternative/addition: which healthcare professions are targeted, etc.)</li> <li>2. Gender, Age (range), other descriptive items</li> </ol>
	2.3 Setting	<ol style="list-style-type: none"> <li>1. Clinical, outpatient setting, at home, other</li> <li>2. Short description of a typical "use case"</li> </ol>
	2.4 Purpose	<ol style="list-style-type: none"> <li>1. Short description of the purpose of the app</li> <li>2. Category: information, reference work, educational resources, documentation, diagnostics, therapy, prevention, research, other</li> <li>3. Basic description of what the app is to be used for, including specific information for the user group(s)</li> </ol>
3. Functionality	3.1 Functions and features	<p>For each available function / feature :</p> <ol style="list-style-type: none"> <li>1. Function (designation)</li> </ol>

		<ul style="list-style-type: none"> <li>1.1 Example</li> <li>1.2 Source(s)</li> <li>1.3 Category: scientifically accepted, up-to-date content and reflects the current state of science and technology, evidence level if applicable</li> </ul>
	3.2 Restrictions and Limits	<ul style="list-style-type: none"> <li>1. Restrictions and limits of the app <ul style="list-style-type: none"> <li>1.1. Specific description of the app's restrictions and limits</li> <li>1.2. Description of potential or existing risks for the user group(s)</li> <li>1.3. Which measures have been implemented to avoid risks for the user group(s)</li> </ul> </li> <li>2. Already known undesirable effects <ul style="list-style-type: none"> <li>2.1. Detailed description of undesirable effects, if any</li> </ul> </li> </ul>
	3.3 Usability	<ul style="list-style-type: none"> <li>1. Methods that were employed during the development cycle <ul style="list-style-type: none"> <li>1.1. Results of usability testing</li> </ul> </li> </ul>
4. Validity and Reliability	4.1 Content	<ul style="list-style-type: none"> <li>1. Information about the expert(s) responsible for the app's content <ul style="list-style-type: none"> <li>1.1. Name of the author(s)</li> <li>1.2. Description of the qualification of the expert(s)</li> <li>1.3. Description of potential or actual conflicts of interest</li> </ul> </li> <li>2. Information about source(s)/reference(s) for all content and algorithms integrated into the app <ul style="list-style-type: none"> <li>2.1. Specific information about the source(s)</li> <li>2.2. Evidence level of the source(s)</li> </ul> </li> <li>3. Studies that have been performed concerning the app <ul style="list-style-type: none"> <li>3.1. Type of the study, references/literature, other evidence</li> </ul> </li> <li>4. Additional material about the app (test reports, etc.) <ul style="list-style-type: none"> <li>4.1. Type of additional material, references links, ...</li> </ul> </li> </ul>
	4.2 Quality assurance	<ul style="list-style-type: none"> <li>1. Information about quality assurance measures that were used during development</li> </ul>
5. Data requisitioning & management	5.1 Data handling	<ul style="list-style-type: none"> <li>1 Data processing <ul style="list-style-type: none"> <li>1.1 Information about data collection mechanisms integrated into the app</li> </ul> </li> <li>2 Data protection &amp; privacy <ul style="list-style-type: none"> <li>2.1 Voluntariness of participating in any data collection</li> </ul> </li> <li>3 Data transmission &amp; storage</li> </ul>

		<p>3.1 Purpose of the data collection</p> <p>3.2 Who profits from the collected data</p> <p>3.3 What kind of and how much data are being collected, at what times (including time intervals where applicable)?</p> <p>In which country is the data being stored? This is especially important considering the differences between data privacy laws and regulations in different countries.</p> <p>3.4 Which methods are being used for storing and evaluating the data?</p> <p>3.5 Specifics about a user's rights to obtain information about any data that is stored about him; in addition, there must be means to revoke an already given permission to store data. For this purpose, a contact address must be specified.</p> <p>3.6 It must also be possible to delete data that has already been stored and the user must be informed about the timespan that is needed until the data is really deleted</p> <p>3.7 Encryption methods and level used for protecting the user's data during transmission, storage and evaluation. It should also be specified whether it is possible to connect a specific user to the stored data or whether the data is being stored anonymously or pseudonymized.</p> <p>3.8 An indication about whether it is possible to prevent data collection and/or transmission and if yes, how this is possible.</p>
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Explanations of the assessment criteria stated in the apps synopsis for "health apps" and "medical apps" as described in Albrecht UV, Pramann O, von Jan U. "Synopsis for Health-Apps - Transparency for Trust and Decision Making" (2013).

<b>Criteria</b>	<b>Content</b>	<b>Rationale</b>
Imprint	Information about the manufacturer/distributor and associates  Meta data of the app	To get in touch, to identify conflicts of interest (influence) of the sponsor and all associated parties.  To get basic information about the actuality of the app.
Rationale	Description of the app's intended purpose(s), targeted user(s), group the dedicated setting of the app, its categorization as a medical/ non-medical	To understand the idea behind the app, its categorization on a professional level and its ideal deployment setting and field of

	app	application.
Functionality	<p>Description on the functionalities and features of the app and the restrictions and limits</p> <p>Details about what measures have been taken to assure good usability of the app</p>	<p>To understand the underlying functions to achieve the app's purpose(s) and its limits and risks to estimate whether the app is safe for usage.</p> <p>To be informed about methods that were employed during the development cycle regarding the app's usability for specific target groups.</p>
Validity and Reliability	<p>Description of which information sources the app is based on and how reliable these are.</p> <p>Description on methods of quality assurance</p>	<p>To assess whether the content and its authors are reliable and whether the functionality base on reliable and valid information sources.</p> <p>To estimate on the level of quality in the production process of the app.</p>
Data requisitioning & management	Description of the amount and types of data that are being collected and processed	To be able to determine whether the app's data collection & processing are adequate to fulfil the stated purpose.
Data protection & privacy:	Information about the manufacturer's adherence to data protection and privacy laws and regulations and the involved jurisdictions	To find out whether the manufacturer provides a privacy statement and data protection policy that is well adapted to the app's purpose.
Data transmission & storage	Description of all measures taken to protect data entrusted to the app	To assess whether data transmission & storage is protected adequately.

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