# OBR Report OBR - v6.0.0

The Assessment Report for:



APP NAME APP VERSION
DrinksRation 3.0.19

DEVELOPER REVIEW COMMENCEMENT DATE

Bitqueen Inc. 07/12/2022

**PLATFORM** ios





APP NAME DrinksRation DEVELOPER Bitqueen Inc.

APP VERSION

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3.0.19
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**PLATFORM** 

**REVIEW TYPE** 

OBR - v6.0.0

### **Overview**

We have reviewed your app and found the following results:

Review Result:	Data: <b>79%</b>	Usability & Accessibility:
Professional Assurance:		
Section Fundamentals		
Scene Setters:	 Data:	Usability & Accessibility:
Passed	Passed	Passed
Professional Assurance:	Reviewer Comments:	
Passed	Passed	
App Categories:  Addiction	Alcoh	ol Awareness
	Alcoh	ol Awareness
	Alcoho	
Addiction  Alcohol Monitoring		

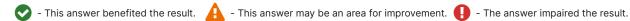
Website:

www.orchahealth.com

### **Scene Setters**

Fundamentals:

## **Passed**









Question Code	Question and Answer	Impact
ORC_SS01	Is the app health focused?	A
	Yes	
ORC_D01	Does the app collect data?	A
	Yes	U
DRC_DT10	What type of data is collected by the app?	
	Name (Full Name, Nickname or First Name Only), Email, Age / DOB, General Identifier eg. NHS	
	No, Marital Status / Family / Lifestyle / Social Circumstance, Employment / Career History,	•
	Usage Data, Race / Ethnic Origin, Physical and/or Mental Health Data, Gender (self-declared or	
	observed)	
DRC_DT14	Are users required to sign up / register to use the service?	<b>A</b>
	Yes	U
ORC_DT13	Is the Data (cookie and/or none cookie) Collected:	A
	Sensitive	
ORC_DC01	How is none cookie data collected?	A
	manual user input, other apps, automatically generated by the app	U
DRC_DC02	What other apps is the App connected to?	<b>A</b>
	Apple Health	U
DRC_DS03	Can/is data shared? (excluding cookies)	<b>A</b>
	Yes	U
DRC_DS04	Can data be shared through a direct, manual action by the user? {e.g. by sending data via	
	email or manually choosing to post/share something within the app etc}	A
	No	

ORC_DS07	Can the user control any automatic data sharing, through setting individual sharing preferences in the app? (excluding cookies)  No	6
ORC_DS09	Is any data (excluding cookie data) shared automatically as soon as the App is accessed – based only on agreement to relevant T&C's or Privacy Policy?  Yes	6
ORC_DS10	Where/With who is data automatically shared - based only on user agreement to the developer's Privacy Policy and/or T&C's?  Developer	6
ORC_DS12	What data is automatically shared with the developer?  Email, Physical and/or Mental Health Data, General Identifier eg. NHS No, Gender (self-declared or observed), Usage Data, Employment / Career History, Age / DOB, Marital Status / Family / Lifestyle / Social Circumstance, Race / Ethnic Origin	6
ORC_DS17	Does the app allow users to access their own NHS personal health records e.g. patient access?	•
ORC_DS18	Does the App appear to access and/or process NHS Patient Information? No	6
ORC_AI01	Does the app contain algorithms? Yes	1
ORC_AI02	How does the app use the algorithm?  The app performs calculations using the users data such as total units, calories and spend.	•
ORC_AI03	Does the app appear to use AI?	6
ORC_I01	Is the app designed to provide information or guidance? Yes	6
ORC_I02	Does the app provide information that is personalised to an end user's specific circumstances?	6
ORC_F08	Does the app provide users with information regarding where they are able to find local or suitable support services?  Yes	6
ORC_F03	Does the app provide environmental data not specific to the patient?	6
ORC_EF07	Does the App provide information, resources or activities to the public, patients or clinicians, either about a specific condition or general health and lifestlye?  Yes	6
ORC_PD01	Is the data the app collects automatically assessed for the purposes of evaluating risk or providing diagnostic support?  No	6

ORC_DG02	Does the app diagnose a specific condition? No	•
ORC_DG04	Does the app provide the option for further assessment or analysis by a healthcare professional?  No	6
ORC_DG05	Is the app/does the app include a Symptom Checker?	6
ORC_TS01	Does the app contain a clinical calculator?	6
ORC_MD01	Is the app intended to be (or does the developer claim it can be) used for the prevention of disease?  No	6
ORC_TS05	Does the app provide treatment of a condition? No	•
ORC_TS07	Does the app guide the treatment of a condition?	6
ORC_TS03	Does the app support healthcare professionals' decisions about treatments?	6
ORC_TS14	Does the app automate the treatment pathway for an individual patient?	6
ORC_TS15	Is the app intended to be (or does the developer claim it can be) used as a physical intervention to reduce the symptoms or severity of a disease, injury or handicap?	1
ORC_MD07	Is the app intended to (or does the developer claim it can be used to) compensate an injury or handicap?  No	1
ORC_CC01	Does the app predict the fertile window?	<b>(i)</b>
ORC_AE20	Is the App used in combination with drugs or medication? {e.g. medication reminders}	<b>(i)</b>
ORC_MN01	Does the app allow the monitoring of key health information?  General Health or Wellness data	<b>(i)</b>
ORC_MN02	Does the app involve the recording of relevant data over time for the user to access and review (with no 'intelligent' manipulation of that data by the app)?  Yes	6
ORC_MN03	Does the app involve the automated assessment or interpretation of relevant data to deliver alerts, insights, reminders or adjustments regarding the user's health or lifestyle?  Yes	•

ORC_MN04	Is the app? a Standard Self Management app?	1
ORC_MN06	Does the app allow others (i.e. not the user) to monitor or view the health data captured?	1
ORC_TS11	What type of intervention or treatment does the app provide?  Monitoring (basic eg. diary)	1
ORC_F14	Can the app be used for patients to have online consultations conversations, or related Health Care services with a healthcare professional?	•
ORC_AS01	Is this an administrative app which does not directly impact patient care?	1
ORC_F13	Does the app allow users to order and request prescriptions?	1
ORC_PC01	Does the App constitute a Pharmacy Service?	1
ORC_D29	Does the app send push notifications? Yes	1
ORC_D30	Does the app send email notifications?	•
ORC_F30	Do any of the features or functions of the app appear to allow it to be used to control a medical device?  No	•
ORC_U19	Are there opportunities to link with other users (buddying, forums or group education)?  No	1
ORC_EF10	Does the App allow two-way communication between citizens, patients or healthcare professionals?  No	1
ORC_F06	Does the app provide gamification or goal setting features for the user? Yes	1
ORC_GS01	Does the app set goals for the user?  Generic	•
ORC_U21	Does the app allow the user to set goals for themselves?	1
ORC_CUS01	Can the app presentation be customised by the user? Yes	1

ORC_CUS02	Does the app respond to preferences in the device? Yes	•
ORC_U29	Is the App totally free? Yes	<b>f</b>
ORC_BM01	How is the app funded? government or similar grants	<b>1</b>
ORC_U27	Does the app contain adverts?	<b>i</b>
ORC_BF01	What are the claimed or implied benefits of the app?  Other Implied Benefit (please describe)	<b>•</b>

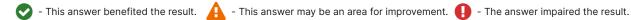
### **Data**

Your Score:

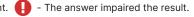
**79%** 

Fundamentals:

## **Passed**









Question Code	Question and Answer	Impact
ORC_D39a	Is there a Privacy Policy clearly available via the App/Web App/Website? Yes	<b>②</b>
ORC_DP03	Is the Privacy Policy made immediately available when the user first opens the app?  No	A
ORC_DP04	Is the policy made available when the user is signing up to use the services?  Yes	<b>②</b>
ORC_DP01	Is it published within the app? Yes	A
ORC_DP02	Is it available externally via the app? No	A
ORC_DP05	Is it available via the relevant app store? Yes	A
ORC_DP06	What data does the Privacy Policy state the developer collects?  Physical and/or Mental Health Data, General Identifier eg. NHS No, Marital Status / Family / Lifestyle / Social Circumstance	<b>i</b>
ORC_DP07	Is the policy accurate, with regards to the data the developer intends to collect?	0

ORC_DP08	How does the developer obtain consent for the processing of user data?  Clear affirmative acceptance option, separate from acceptance of other terms and conditions and/or consent requests	•
ORC_DP14	Does the Privacy Policy Provide the name and contact details of their Data Protection Officer (DPO), or similar individual representative for the company?  Yes	•
ORC_DP15	Provide the details of the DPO:  KCL Data Protection Officer: Mr Albert Chan (Assistant Director of Business Assurance)  Information Compliance team: King's College London, Waterloo Campus Room 5.20, James  Clerk Maxwell Building, 57 Waterloo Road, London, SE1 8WA; or by email: info-  compliance@kcl.ac.uk	6
ORC_D69	Does the developer fully inform the user of how they will collect data about them? Eg. Directly from the user or through third party sources  Yes	•
ORC_D13	Does the developer provide users with details on all the purposes of processing user data?  Yes	<b>⊘</b>
ORC_DP10	What is automatically shared data used for? research	6
ORC_D38	Does the developer appear to intend to share or process the user data collected by the app for any purposes that have not been made clear to the user, or for any purposes they deem necessary?  No	•
ORC_D71	Does the developer inform users that they would like to use their data for the purpose of marketing, or providing information on products or services that might be of interest to the user?  No	•
ORC_DP13	If the user can not opt out of all processing activity, does the developer clearly explain which activities the cannot opt out of and why?  Yes	•
ORC_D16	Is the user informed that their data will not be shared with other parties, except for the purposes that have been set out in the privacy policy?  Yes	•
ORC_DST01	Does the data privacy policy or equivalent provide detail about where the data collected by the app will be stored (i.e. on the app or in an external data warehouse, cloud server etc.)?  Yes	•
ORC_DST02	Where is the data stored?  All electronic information will be held securely on encrypted servers.	1
ORC_DST03	Does the Data Privacy Policy, or equivalent, state whether personal data is stored using recognised secure data storage technologies?  Yes	A

ORC_D17	Is all personally identifiable data encrypted in transit between the device and any external host storage?  Yes	•
ORC_DM01	Does the policy state its compliance with recognised International Data Management Standards? (ISO, BSI)?  None	A
ORC_D19	Is there a policy or statement that contains details of the length of time data will be retained for?  Yes	<b>©</b>
ORC_D20	Is there a policy or statement that details the developer's intentions for data destruction?  Yes	<b>②</b>
ORC_D21	Is there a policy or statement that sets out a process for managing data confidentiality breaches?  Yes	•
ORC_D23	Is there a policy or statement that confirms the App's compliance with GDPR? Yes	<b>②</b>
ORC_D60	Is the user informed of the legal basis for which data is collected from them? i.e. Consent, Performance of Contract, Legal Obligation, Vital Interests, Public Interest or Legitimate Interest. Please Specify. Yes	<b>©</b>
ORC_DPR03	Is the user informed that the developer will only collect minimum data items that are necessary to provide their services, therefore ensuring data minimisation principles are met?  Yes	<b>©</b>
ORC_D61	Is there a statement that the policy will be updated if there is a change in the purpose of data collection? This may mean re-obtaining user consent (if consent was the lawful basis).  Yes	•
ORC_DPR01	Are users informed of their rights with regards to their data? Yes	•
ORC_D93	Has the developer made the existence of the data subject's right to request that their personal data is deleted clear?  Yes	•
ORC_D25	Has the developer made the existence of the data subject's right to access their personal data clear? Yes	<b>②</b>
ORC_D56	Has the developer made the existence of the data subject's right to rectify their personal data clear?  No	A
ORC_D81	Has the developer made the existence of the data subject's right to restrict the use of their personal data clear?  Yes	•

ORC_D57	Has the developer made the existence of the data subject's right to object to the processing of his/her personal data clear? Yes	•
ORC_D59	Has the developer made the existence of the data subject's right to portability of their personal data clear?  No	A
ORC_D58	Has the developer made the existence of the data subject's right to withdraw consent for the use of their personal data clear?  No	A
ORC_DPR02	Has the developer made clear the existence of the user's right to request that they are not subject to a decision based solely on automated processing, including profiling, which produces legal/significant effects concerning the user?  No	A
ORC_D82	Does the developer provide details that the user can contact them on to exercise their rights?  Yes	<b>Ø</b>
ORC_D83	Is the user informed of the time frame in which the developer will respond to any requests to exercise their rights? This time frame should be within two months of receipt of any request.	A
ORC_D44	Is the app 'particularly likely' to be used by children, even if they are not the primary market for the app?  No	6
ORC_DO01	Are users informed of how they can report, to the developer, any knowledge of a child accessing the app and providing personal data, without parental consent?  Yes	•
ORC_D91	Is the user made aware that by following links to third party websites, the developer's policies no longer apply and that the user should make themselves aware of the third party's policies?  Yes	<b>②</b>
ORC_D92	Is the user informed of how they can make further enquiries about the company's privacy policy?  Yes	<b>②</b>
ORC_D06	Does the app allow the user to set their preferences for sharing the app data with or from other apps (e.g. Facebook / Instagram/Fitbit etc)?  No	A
ORC_DO02	Is it strictly necessary for anyone to easily access the information that persists on the app? eg. to access health info during an emergency  No	6
ORC_DO03	Are users provided options to introduce additional security measures to protect their data on the app? eg. set additional pass codes for access to the app, after accessing the device is unlocked.  No	A

ORC_DO04	Does the app use a sign up/sign in verification/authentication model?  Yes	•
ORC_DO05	What type of model is being used?	
	One-step email authentication, HCP Granted Access/Invite	

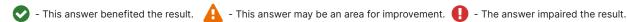
# Usability & Accessibility

Your Score:

83%

Fundamentals:

### **Passed**









Question Code	Question and Answer	Impact
ORC_DE01	Is there a statement within the app outlining compliance with any currently recognised app design standards?  None	A
ORC_DT01	Is there a statement within the app or store about user feedback during design and/or development?  Yes	•
ORC_DT02	Is there a statement either in the app or store about user involvement in testing? Yes	•
ORC_U04	Can the user change the font size within the App or does the app respond to font preferences in the device?  No	A
ORC_U07	Does the app provide support options for users with poor sight? Yes	•
ORC_U08	Does the app provide support options for users with hearing difficulty? Yes	•
ORC_U06	Can the user change the presentation theme? Yes	•

ORC_U32	Does the app include the following functions:  Home/Menu button, Help/About button	1
ORC_U15	Are any clinical or technical terms used explained clearly to the user? (either within the content of the app or via a glossary)  Yes	•
ORC_D31	Does the user have options to manage the notification settings for push/email notifications within the app for convenience/privacy?  Yes	•
ORC_D32	Does the app inform the user how to manage notification settings for convenience / privacy (eg to prevent divulging personal information if the device is locked but on show?)  Yes	•
ORC_U23	During review, was there any evidence of bugs? No	<b>②</b>
ORC_U24	Is there any statement or evidence of how to report issues to the developers? (e.g. this may be a help button with contact form, instructions or email details)  Yes	1
ORC_U33	What kind of support is offered? eTicket	•
ORC_U25	Is there any statement within the app about the developer's commitment to addressing problems reported to them? (e.g. timescales to respond, commitment to eradicate reported bugs and faults)  No	A
ORC_UX01	Does the Developer publish or make available unedited User Feedback Data? No	A
ORC_UX02	Does the Developer publish or otherwise make available any unedited user usage Data?	A

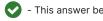
## **Professional Assurance**

Your Score:

80%

Fundamentals:

**Passed** 









Question Code	Question and Answer	Impact
ORC_MD11	Is the app a medical device? (autofill but there to validate) No	<b>i</b>
ORC_FDA01	Has the app been FDA approved?	<b>i</b>
ORC_FDA02	Has the app been FDA cleared?	<b>i</b>
ORC_ESF05	Is the app ESF Tier 3b?	<b>i</b>
ORC_ESF04	Is the app ESF Tier 3a?	<b>i</b>
ORC_ESF03	Is the app ESF Tier 2b? Yes	<b>i</b>
ORC_ESF02	Is the app ESF Tier 2a?	<b>i</b>
ORC_ESF01	Is the app ESF Tier 1? No	<b>i</b>

ORC_EE02	What type/s of evidence is available? RCT	•
ORC_EE14	How many pieces of evidence does the app provide? One	<b>(1)</b>
ORC_EE13	How many RCT's and/or observational studies does the app have? One	<b>(1)</b>
ORC_EE10	What category does the evidence relate to? Alcohol consumption	<b>(1)</b>
ORC_EE11	What benefit does the evidence relate to?  Reductions in alcohol consumption	6
ORC_EE03	Provide links to the publicly available evidence/published evidence that the developer has provided.  Leightley, D., Rona, R.J., Shearer, J. et al (2020) Evaluating the Efficacy of a Mobile App (Drinks:Ration) and Personalized Text and Push Messaging to Reduce Alcohol Consumption in a Veteran Population: Protocol for a Randomized Controlled Trial. JMIR Publications. https://www.researchprotoce19720ols.org/2020/10/	1
ORC_EE04	Is the sample size appropriate? Yes	6
ORC_EE05	Does the evidence found provide a p-value or Confidence Interval (CI)? Yes	•
ORC_EE06	Does the P-Value demonstrate significance (p<0.05)? Yes	6
ORC_EE07	Is there a comparator? Yes	<b>f</b>
ORC_EE08	Is the comparator validated? No	•
ORC_PB01	Is there a suitably qualified Professional involved in the Development team of the App?  Yes	•
ORC_PB02	Has the app been developed by a recognised or national health body? Yes	•
ORC_PB03	Is there evidence of an endorsement by a relevant body?	A
ORC_PB04	Are organisations using the App? No	A
ORC_PB05	Is there a statement that it has been positively evaluated or validated by a relevant healthcare professional?  No	A

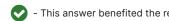
ORC_PB06	Is there evidence within the app that the developer has validated any guidance with relevant reliable information sources or references?  Yes	•
ORC_S01	Does the Developer clearly identify who the app should be used by? Yes	•
ORC_S02	Does the Developer publish their risk management processes?	A
ORC_S03	Does the Developer make clear risks associated with using the app? No	A
ORC_S04	Is there a way for the user to confirm that the data input is accurate?  No	0
ORC_S05	Does the Developer list a Clinical Safety Officer on/in any relevant sites/content?  No	A
ORC_ESF06	Has the app met Tier 1 minimum requirements? Yes	A
ORC_ESF07	Has the app met Tier 2a minimum requirements? Yes	A
ORC_ESF08	Has the app met Tier 2b minimum requirements? Yes	<b>②</b>
ORC_ESF09	Has the app met Tier 3a minimum requirements? Yes	A
ORC_ESF10	Has the app met Tier 3b minimum requirements? No	A
ORC_ESF11	Does the app have appropriate evidence for the ESF tier? Yes	6

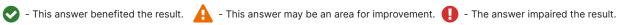
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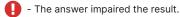
## Reviewer **Comments**

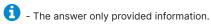
Fundamentals:

### **Passed**









Question Code	Question and Answer	Impact
ORC_RC01a	Would you like to provide any additional review notes for the sign off and/or further discussion?  No	6
ORC_RC02a	Would you like to provide any additional app review notes to be displayed on the developer report and website?  No	•