## **Supplementary Online Content**

Hooton TM, Vecchio M, Iroz A, et al. Effect of increased daily water intake in premenopausal women with recurrent urinary tract infections: a randomized clinical trial. Published online October 1, 2018. *JAMA Intern Med.* doi:10.1001/jamainternmed.2018.4204

**eMethods 1.** 3-days Fluid Intake Diary **eMethods 2.** Voiding Diary

This supplementary material has been provided by the authors to give readers additional information about their work.



Subject Number: 1 0 0 - 0 0 1 - |\_\_|\_\_|

### eMethods 1. 3 DAYS FLUID INTAKE DIARY

Subject Identification:	100 - 001	·
-------------------------	-----------	---

Dear Ms.,

You just have been selected to participate to the study NU369.

Depending on the visit number, you will be provided with the corresponding pages of this diary. You will have to fill in it until the end of this study.

This diary will be useful for you to specify data that will be very important for the analysis of these study results.

Please take few minutes to read it carefully. It contents important information that will be useful to ensure the accuracy of the final results of this study.

We thank you for your participation.

The S\_HYDRACYST Project team.



Subject Number: 1 0 0 - 0 0 1 - |\_\_|\_\_|

### ADDRESSES AND CONTACT INFORMATION

Principal Investigator: MAYA DABCHEVA, MD COMAC MEDICAL LTD, SOFIA, BULGARIA

PHONE: +359 2 850 97 04



# Subject Number: 1 0 0 - 0 0 1 - | |

Thank you very much for participating in our study. We would like to

ask you to write down everything you drink during the day (beverage, quantity and context). For this purpose we have prepared "a beverages fluid intake". Its fulfillment won't take you more than a few minutes per day. The diary is divided into 13 months. We ask



you to fulfill it for 3 consecutive days including 2 days of the week-end and 1 working day (Saturday - Sunday - Monday or Friday - Saturday - Sunday) each month.

Here are some advices to complete correctly the diary. For any additional information, feel free to contact the investigative site.



#### Golden rules:

Filling in this diary, please note that:

- The Diary has been prepared to record in detail what you drank for 3 consecutive days.
- Please write everything you drank during the whole day regardless of whether it was at home or not.
- Each consumed beverage should be entered on a separate line. Please write any type of beverage: juice, water, tea, beer, etc...
- For each moment of the day you have the possibility to enter several types of consumed beverages.
- Please carry out a systematic diary if possible without leaving it for the end of the day. Otherwise, there is a risk that you forget a few important details.

© 2018 Hooton TM et al. JAMA Intern Med.



Subject Number:	
100-001-	

### DAYS AND OCCASIONS

Each day of the diary is divided into different moments of the day. At any moment of the day, please think about ALL the beverages you drank and enter them in the appropriate lines.

Moments of the day:

- 1. After wake up, Before breakfast
- 2. During breakfast
- 3. Between breakfast and lunch
- 4. During lunch
- 5. Between lunch and dinner
- 6. During dinner
- 7. After dinner
- 8. During the night

### HOW TO FILL IN THIS DIARY

For each beverage consumed, please record the following information:

- A) Type of drink
- B) Beverage packaging
- C) The amount of beverage consumed



Subject Number:					
100-001-					

#### **Beverage Type - Column A**

In column A of the diary, please enter the number in front of the kind of beverage that you drank

#### WATER

- 1. Tap water
- 2. Bottled non-carbonated mineral water (including the water drank for the study if you are in the intervention group- )
- 3. Bottled carbonated mineral water
- 4. Water from distributor\big bottle

#### **HOT DRINKS**

- 5. Coffee
- 6. Hot chocolate, Cacao, Cappuccino
- 7. Tea (black)
- 8. Fruit tea
- 9. Green tea
- 10. Other Tea

#### **MILK DRINKS**

- 11. Milk (full\skimmed)
- 12. Buttermilk, kefir
- 13. Drinking yoghurt
- 14. Other milk drinks

#### **SUGARED BEVERAGES**

- 15. 100% fruit juice
- 16. Thick mashed juice, usually based on carrot or banana (i.e. Kubus, Pysio)
- 17. Vegetable juice (i.e. tomato)
- 18. Fruit nectar
- 19. Fresh juice one or two-days (i.e. Marvit)
- 20. Fresh juice prepared at home (squeezed)
- 21. Compote
- 22. Fruit non-carbonated drinks

© 2018 Hooton TM et al. JAMA Intern Med.



### Subject Number: 1 0 0 - 0 0 1 - |\_\_|\_\_|

- 23. Ice Tea
- 24. Ice Coffee
- 25. Energetic drinks (i.e. Red Bull)
- 26. Isotonic drinks, for sportsmen (i.e. Isostar, Powerade)
- 27. Carbonated cola type drink
- 28. Other carbonated drink fruit, tonic, orangeade (i.e. Fanta, Sprite)

#### **DIET BEVERAGES**

- 29. Fruit non-carbonated drinks
- 30. Diet Ice Tea
- 31. Diet Ice Coffee
- 32. Diet Energetic drinks (i.e. Red Bull)
- 33. Diet Carbonated cola type drink
- 34. Other diet carbonated drink fruit, tonic, orangeade (i.e. diet Fanta, diet Sprite)

#### **ALCOHOL**

- 35. Beer
- 36. Wine
- 37. Aperitif, Cocktail, Liqueur, Drink
- 38. High percentage alcohol (vodka, cognac, whisky)

#### **OTHER**

39. Other



Subject Number:					
100-001-	_				

#### Drink package - Column B

Please enter the code for the packaging corresponding to the drink you entered on columns A and B

#### **TETRA PACK**

- 01. Tetra pack 0,2 L
- 02. Tetra pack 0,25 L
- 03. Tetra pack 0,33 L
- 04. Tetra pack 0,5 L
- 05. Tetra pack 1 L
- 06. Tetra pack 1,5 L
- 07. Tetra pack 2 L

#### **PLASTIC BOTTLE**

- 08. Plastic bottle 0,25 L
- 09. Plastic bottle 0,33 L
- 10. Plastic bottle 0,5 L
- 11. Plastic bottle 0,7 L /0,75 L
- 12. Plastic bottle 1 L
- 13. Plastic bottle 1,5 L
- 14. Plastic bottle 2 L
- 15. Plastic bottle 5 L

#### **GLASS BOTTLE**

- 16. Glass bottle 0,2 L
- 17. Glass bottle 0,25 L
- 18. Glass bottle 0,33 L
- 19. Glass bottle 0,5 L
- 20. Glass bottle 0,66 L
- 21. Glass bottle 0,75 L
- 22. Glass bottle 1 L

#### CAN

- 23. Can 0,33 L
- 24. Can 0,5 L

#### **OTHER**

25. Other



Subject Number: 1 0 0 - 0 0 1 - |\_\_|\_\_|

#### Amount of drank drink - Column C

Please enter the quantity of beverage consumed at a given moment in litres for example:

If you drank a can of cola => please write 0,33 L

If you drank a glass of water from the 1.5 L bottle => please write **0,25L** To help you, you will find below a table of various sizes commonly used:

Standard glass – 0,25 L
Mug – 0,25 L
Cup of coffee – between 0,1 and 0,2 L
Glass of vodka –40 mL
Glass of wine – between 0,15 L to 0,25 L.

Please fill in the diary as described above.

When entering the beverages drunk you should always take into account the day and the different moments of the day.

#### THANK YOU FOR YOUR HELP AND COOPERATION!!

© 2018 Hooton TM et al. JAMA Intern Med.



Month 0

Subject Number:						
100-001-  _						

### Fluid consumption report: Month 0

You	should	decide	when	to	start	completing	the	diary	on	three
cons	ecutive	days for	this m	ontl	h: on	Friday or on	Satu	rday. I	Depe	ending
on y	our choi	ce, you	will co	mple	ete it o	on: <i>(please t</i>	ick th	e corr	espo	onding
box	below)									

( - · · · ( - ( - · · · )	, ,	•		
box below)				
□ Friday – S	aturday - Su	ınday		
OR on				
□ Saturday -	- Sunday - N	<i>l</i> londay		
_	_	_		
	Date (DD/M	M/YYYY):  _	_  /  _ /	_ _ _

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, _ L
1 After wake up, Before breakfast			_, L
		<u> </u>	_, L
		<u> </u>	_, L
2 During breakfast		<u> </u>	_, L
			_, L
			_, L
3 Between breakfast and lunch			_, L
			_,L



Month 0

	 	_, _ L
4 During lunch		_, L
		_, L
	 	_, L
5 Between lunch and dinner		_, L
	 	_, L
		_, L
6 During dinner		_, L
		_, L
	 	_, L
7 After dinner		_, L
	 	_, L
8 During the night	 	_,L
	 	_, L
	 	_,L



Subject Number: 1 0 0 - 0 0 1 -

Date (DD/MM/YYYY)	):		/	<u> </u>	/ _	_ _	<u> </u>	
-------------------	----	--	---	----------	-----	-----	----------	--

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, _ L
1 After wake up, Before breakfast			_, L
			_, _ L
			_, _ L
2 During breakfast			_,L
			_,L
			_,L
3 Between breakfast and lunch			_, _ L
			_, _ L



Subject Number:							
1	0 0	- 0	0 1	-			
			<u> </u>				

	-	-	_, L
4 During lunch	-	-	_, L
			_, L
	-		_, L
5 Between lunch and dinner	-		_, L
	-		_, L
	-		_, L
6 During dinner	1		_,
		-	_, L
		-	_, L
7 After dinner		-	_, L
	1	-	_, L
			_, L
8 During the night			_, L
			L



Subject Number:						
1	0 0 - 0 0 1 -    _					

Date (DD/MM/YYYY)	: [	I_	//	<u> </u>	<u> </u>	/		<u></u>			I
-------------------	-----	----	----	----------	----------	---	--	---------	--	--	---

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
		-	_, L
1 After wake up, Before breakfast			_, _ L
			_, _ L
			_, _ L
2 During breakfast			_, _ L
			L
			_, L
3 Between breakfast and lunch			_, _ L
			_, _ L



Month 0

	 	_, _ L
4 During lunch	 	_, _ L
	 	_, _ L
	 	_, _ L
5 Between lunch and dinner	 	_, _ L
	 	_, _ L
	 	_, _ L
6 During dinner	 	_, _ L
	 	_, _ L
	 	_, _ L
7 After dinner	 	_, _ L
7 Alter diffici	 	_, _ L
	 	_, _ L
	 	_, _ L
8 During the night	 	_, _ L
	 	_, _ L



Month 0

Subject Number:					
100-001-  _					

### **NOTES**

Have you undergone an adverse event during this month? If yes, please describe it briefly here as follows:

Have you taken any medication (including medications taken for treatment of an adverse event)? If yes, please specify in the following table:

Medication	Start of administration	End of administration	Dose/Frequency

Remember to send back the diary at the investigating site by courier, using the pre-print envelope or to give it personally if more convenient for you.



Month 0

	Validated by the i	nvestigator	
Signature			Date
(justify any corre	ection performed durir	ng the review of the	e document)



Month 1

Subject Number:					
100-001-	_				

### Fluid consumption report: Month 1

You should decide when to start completing the diary on three consecutive days for this month: on Friday or on Saturday. Depending on your choice, you will complete it on: (please tick the corresponding box below)
□ Friday – Saturday - Sunday
OR on
□ Saturday – Sunday - Monday
Date (DD/MM/YYYY):   _ / _ _ / _ _

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, _ L
1 After wake up, Before breakfast			_, _ L
			_, L
			_, _ L
2 During breakfast			_, _ L
			L



Month 1

_		
	-	_, L
3 Between breakfast and lunch	-	_, _ L
	-	_, L
	-	_, L
4 During lunch	-	_, _ L
	 	_, _ L
	 	_, _ L
5 Between lunch and dinner	 	_, _ L
	 	_, _ L
	 	_, _ L
6 During dinner	 	_, _ L
	 	_, _ L
	 	_, _ L
7 After dinner	 	_, _ L
	 	_, _ L
	 	_, _ L
8 During the night	 	_,L
	 	L



Subject Number:	
100-001-	

Date (DD/MM/YYYY):  _	_ _	/		′I				ı
-----------------------	-----	---	--	----	--	--	--	---

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, _ L
1 After wake up, Before breakfast			_, _ L
			_, _ L
			_, _ L
2 During breakfast			_, _ L
			_,L
			_,L
3 Between breakfast and lunch			_,L
			_,L



Month 1

	 	_, L
4 During lunch	 	_, _ L
	 	_, L
	 -	_, L
5 Between lunch and dinner	 -	_, L
	 -	_, L
	 	_, L
6 During dinner	 	_,L
	 	_, L
	 	_, _ L
7 After dinner	 	_, _ L
	 	_, _ L
	 	_, _ L
8 During the night	 	_, _ L
	 	_,L



Subject Number:	
100-001-	

<b>Date</b>	(DD/MM/YYYY	):		/	ı	/	i	ı	l	I

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, L
1 After wake up, Before breakfast			_, L
			_, _ L
			_, L
2 During breakfast			_, L
			_, _ L
			_, L
3 Between breakfast and lunch			_, _ L
			_, _ L



Month 1

	 	_, _ L
4 During lunch	 	_, _ L
	 	_, L
	 -	_, L
5 Between lunch and dinner	 	_, L
	 	_, _ L
	 	_, _ L
6 During dinner	 	_, L
	 	_, L
	 	_, L
7 After dinner	 	_, L
	 	_, L
	 	L
8 During the night	 	L
	 	_, _ L



Month 1

Subject Number:
100-001-

# Notes

descri	you undergone a be it briefly here s:	as	t during this mor	nth? If yes, please			
		edication (includ /es, please also		taken for treatme llowing table:	nt of		
	Medication	Start of	End of	Dose/Frequency			
		administration	administration				
				site by courier usir			
		Validated by t	he investigator				
Signa	ture			Date			
(j	ustify any correc	ction performed o	during the reviev	v of the document	)		



Month 2

Subject Number: 1 0 0 - 0 0 1 - |\_\_|\_\_|

### Fluid consumption report: Month 2

You	should	decide	when	to	start	compl	leting	the	diary	on	three
cons	ecutive	days for	this m	ontl	h: on	Friday	or on	Satu	rday.	Depe	nding
	our choi below)	ce, you	will cor	nple	ete it	on: <i>(ple</i>	ease ti	ck th	e corr	espo	nding
DOX I	Jelow)										

box below)
□ Friday – Saturday - Sunday
OR on
□ Saturday – Sunday - Monday
Date (DD/MM/YYYY):   _ / _ / _ / _

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, _ L
1 After wake up, Before breakfast			_, _ L
			_, _ L
			_,L
2 During breakfast			_,L
			L



Month 2

			_, _ L
3 Between breakfast and lunch			_, _ L
			_, _ L
			_, _ L
4 During lunch			_, _ L
			_, _ L
			_, _ L
5 Between lunch and dinner			_, _ L
			_,L
			_,L
6 During dinner			_, _ L
			_, _ L
			_, _ L
7 After dinner			_, _ L
			_,L
			_,L
8 During the night			_,L
			_, L



Subject Number:	
100-001-  _	

Date (DD/MM/YYYY):			/	<u></u>	/		<u></u>			ı
--------------------	--	--	---	---------	---	--	---------	--	--	---

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, L
1 After wake up, Before breakfast			_, L
			_, _ L
			_, L
2 During breakfast			_, L
			_, _ L
			_, L
3 Between breakfast and lunch			_, _ L
			_, _ L



Month 2

	 	_, L
4 During lunch	 	_, L
	 	_, L
	 	_, L
5 Between lunch and dinner	 	_, L
	 	_, L
	 	_, _ L
6 During dinner	 	_, _ L
	 	_, _ L
	 	_, L
7 After dinner	 	_, _ L
	 	_, _ L
8 During the night	 	_, _ L
	 	_, _ L
	 	_, L



Subject Number	er:
100-001-	

Date (DD/MM/YYYY):	<u>                                   </u>	/	/		_	.
--------------------	--	---	---	--	---	---

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, _ L
1 After wake up, Before breakfast			_, L
			_, _ L
			_, _ L
2 During breakfast			_, _ L
			_,L
			_,L
3 Between breakfast and lunch			_, _ L
			_, _ L



Month 2

	1		_, _ L
4 During lunch		-	_, L
		-	_, L
			_, L
5 Between lunch and dinner		-	_, L
			_, L
6 During dinner		-	_, L
	-		_, L
	-		_, L
	-		_, L
7 After dinner	-		_, L
			_, L
8 During the night			_, _ L
			_, _ L
			_,L



Month 2

Subject Numbe	r:
100-001-	_ _

# Notes

	Have you undergone an adverse event during this month? If yes, please describe it briefly here as follows:					
			ling medications cify in the followir End of administration	taken for treatmeng table:  Dose/Frequency	nt of	
	Remember to send back the diary at the investigating site by courier using the pre-print envelope or to give it personally if more convenient for you.					
		Validated by t	he investigator			
Signa	Signature Date					
(j	(justify any correction performed during the review of the document)					



Month 3

Subject Num	ber:
100-001-	_  _

### Fluid consumption report: Month 3

You	should	decide	when	to	start	compl	leting	the	diary	on	three
cons	ecutive	days for	this m	ontl	h: on	Friday	or on	Satu	rday.	Depe	nding
	our choi below)	ce, you	will cor	nple	ete it	on: <i>(ple</i>	ease ti	ck th	e corr	espo	nding
DOX I	Jelow)										

Date (DD/MM/YYYY):   _ / _  / _ _
☐ Saturday – Sunday - Monday
OR on
☐ Friday – Saturday - Sunday

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, _ L
1 After wake up, Before breakfast			_, _ L
			_, _ L
			_,L
2 During breakfast			_,L
			L



Month 3

			_, _ L
3 Between breakfast and lunch			_, _ L
			_, _ L
			_, _ L
4 During lunch			_, _ L
			_, _ L
			_,L
5 Between lunch and dinner			_, _ L
			_, _ L
			_, _ L
6 During dinner			_, L
			_, L
			_, L
7 After dinner	1		_, L
	1		_, L
			_, L
8 During the night			_, L
			_, _ L



	Subject Number:	
1	00-001-  _	

Date (DD/MM/YYYY):  _		/	.	/			<u></u>	١
-----------------------	--	---	---	---	--	--	---------	---

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, L
1 After wake up, Before breakfast			_, L
			_, _ L
			_, _ L
2 During breakfast			_, L
			_,L
			_, L
3 Between breakfast and lunch			_, _ L
			_, _ L



Month 3

	 	_, L
4 During lunch	 -	_, L
	 -	_, L
	 	_, L
5 Between lunch and dinner	 	_, L
	 	_, _ L
	 	_, _ L
6 During dinner	 	_, _ L
	 	_, _ L
	 	_, _ L
7 AfterAfter dinner	 	_, _ L
	 	_, _ L
	 	_, _ L
8 During the night	 	_, _ L
	 	_,L



Subject Number:				
100-001-				

Date (DD/MM/YYYY):   _ /  /  /
--------------------------------

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
1 After wake up, Before breakfast			_, _ L
			_, L
			_, _ L
2 During breakfast			_, _ L
			_, _ L
			_,L
3 Between breakfast and lunch			_,L
			_,L
			_,L
4 During lunch			_, _ L
			_, _ L
			_, _ L



Month 3

Subject Number:						
100-001-						

_		
		 _, _ L
5 Between lunch and dinner		 _, _ L
		 _, _ L
		 _, _ L
6 During dinner		 _, _ L
		 _, _ L
		 _, _ L
7 After dinner	-	 _, L
	-	 _, L
		 _,L
8 During the night		 _,L
		 _,L



Month 3

Subject Number:						
1	0 0	- 0	0	1	-	

# **N**OTES

Have you undergone an adverse event during this month? If yes, please describe it briefly here as follows:							
				taken for treatme	nt of		
an adv	verse event)? If y				1		
	Medication	Start of	End of	Dose/Frequency			
		administration	administration				
					1		
					J		
				site by courier usin			
		Validated by t	he investigator				
Signa	ture			Date			
(j	ustify any correc	tion performed o	during the review	v of the document	·)		



Month 4

Subject Number:							
100-001-							

#### Fluid consumption report: Month 4

You should decide when to start completing the diary on three consecutive days for this month: on Friday or on Saturday. Depending on your choice, you will complete it on: (please tick the corresponding box below)

,								
□ Friday – Saturday - Sunday								
OR on								
□ Saturday – Sunday - Monday								
Date (DD/MM/YYYY): I	ı	1/1	ı	1/1	ı	ı	ı	ı

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, _ L
1 After wake up, Before breakfast			_, L
			_, L
			_, L
2 During breakfast			_, L
			_, _ L



Month 4

_		
	 	_, L
3 Between breakfast and lunch	 	_, _ L
	 	_, _ L
	 -	_, _ L
4 During lunch	 -	_, L
	 -	_, _ L
	 -	_, _ L
5 Between lunch and dinner	 -	_, _ L
	 	_,L
		_, L
6 During dinner		_, L
		_, L
		_, L
7AfterAfter dinner	 	_,L
	 	_,L
	 	_, _ L
8 During the night	 	_,L
	 	_, _ L



Month 4

Date (DD/MM/YYYY):  _	_ _	/		′I				ı
-----------------------	-----	---	--	----	--	--	--	---

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, _ L
1 After wake up, Before breakfast			_, L
			_, _ L
			_,L
2 During breakfast			_,L
			_,L
			_,L
3 Between breakfast and lunch			_,L
			_, _ L
			_, _ L
4 During lunch			_, _ L
			_,L



Month 4

	1	 _, L
5 Between lunch and dinner	1	 _, L
		 _, L
		 _, L
6 During dinner	_	 _, L
		 _, L
	1	 _, L
7 After dinner	1	 _, L
	1	 _, L
		 _, L
8 During the night		 _, _ L
		 _, L



Month 4

Subject Number:								
1	0 0	- 0	0 1	-				

Date (DD/MM/YYYY):			/			/			<u></u>		
--------------------	--	--	---	--	--	---	--	--	---------	--	--

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, _ L
1 After wake up, Before breakfast			,L
			_, _ L
			_, _ L
2 During breakfast			_, _ L
			_,L
			_,L
3 Between breakfast and lunch			_,L
			_, _ L
			_,L
4 During lunch			_, _ L
			L



Month 4

Subject Number: 1 0 0 - 0 0 1 - |\_\_|\_\_|

		 _, _ L
5 Between lunch and dinner		 _, _ L
		 _, _ L
		 _, _ L
6 During dinner		 _, _ L
		 _, _ L
	-	 _, _ L
7 After dinner	1	 _, _ L
		 _, _ L
8 During the night		 _, _ L
		 _, _ L
		 _,L

# **NOTES**

describe it briefly here as	s follows:	
•••••		•

© 2018 Hooton TM et al. JAMA Intern Med.

DANON RESEAR CENTRE DAI	E CH NIEL CARASSO	S_HYDRACYST	Month 4	1 0 0 - 0 0 1 -
		n any medication (in nt)? If yes, please sp		dications taken for treatment of following table:
	Medicati	on Start of administration	End of administr	Dose/Frequency ration
				vestigating site by courier nally if more convenient for
		Validated b	y the investi	igator
Signa	ture			Date
(j	ustify any	correction performe	ed during the	e review of the document)

Month 4

NU369



Month 5

Subject Number:	
100-001-	

# Fluid consumption report: Month 5

You	should	decide	when	to	start	completing	the	diary	on	three
cons	ecutive	days for	this m	ontl	n: on	Friday or o	n Satu	ırday. 🛚	Depe	ending
	our choi be <i>low)</i>	ce, you	will cor	nple	ete it (	on: (please	tick th	ne corr	espo	onding

Date (DD/MM/YYYY):   _ /  /  / _
□ Saturday – Sunday - Monday
OR on
□ Friday – Saturday - Sunday
box below)

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_,L
1 After wake up, Before breakfast			_,L
			_, L
			_, L
2 During breakfast			_, L
			_, _ L



Month 5

_		
	 	_, L
3 Between breakfast and lunch	 	_, L
	 	_, _ L
	 -	_, _ L
4 During lunch	 	_, _ L
	 -	_, _ L
	 -	_, _ L
5 Between lunch and dinner	 -	_, _ L
	 	_,L
		_, L
6 During dinner		_, L
		_, L
		_, L
7 After dinner		_, L
	 	_,L
	 	_, _ L
8 During the night	 	_, _ L
	 	_, _ L



Month 5

Date (DD/MM/YYYY):	<u>                                   </u>	/	/		_	.
--------------------	--	---	---	--	---	---

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, _ L
1 After wake up, Before breakfast			_, _ L
			_, _ L
			_, _ L
2 During breakfast			_, _ L
			_, _ L
			_, _ L
3 Between breakfast and lunch			_, _ L
			_, _ L
			_,L
4 During lunch			_, _ L
			_,L



Month 5

			_,L
5 Between lunch and dinner	1	-	_, _ L
		-	_, _ L
			_,L
6 During dinner	-		_, _ L
			_, _ L
	1		_, _ L
7 After dinner	1	-	_, _ L
	1	-	_, _ L
			_,L
8 During the night			_,L
			_, _ L



Month 5

Subject Number:				
100-001- _	_			

Date (DD/MM/YYYY):	<u>                                   </u>	/	/		_	.
--------------------	--	---	---	--	---	---

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, _ L
1 After wake up, Before breakfast			_, _ L
			_, _ L
			_,L
2 During breakfast			_,L
			_,L
			_,L
3 Between breakfast and lunch			_,L
			_, _ L
			_, _ L
4 During lunch			_, _ L
			_,L



Month 5

Subject Number: 1 0 0 - 0 0 1 - |\_\_|\_\_|

			_, _ L
5 Between lunch and dinner			_, _ L
			_, _ L
			_, _ L
6 During dinner			_, _ L
	-		_, _ L
	1		_, _ L
7 After dinner		-	_, _ L
			_, _ L
			_, _ L
8 During the night			_, _ L
			_, _ L

# Notes

Have you undergone an adverse event during this month? If yes, please describe it briefly here as follows:			
	• •		
	٠.		
	٠.		
	٠.		
	• •		
	٠.		

© 2018 Hooton TM et al. JAMA Intern Med.

•
DANONE RESEARCH
CENTRE DANIEL CARASSO

Month 5

Subject Number:				
100-001	-   _			

	Medication	Start of administration	End of administration	Dose/Frequency		
				site by courier using t		
Validated by the investigator Signature Date						
(justify any correction performed during the review of the document)						



Month 6 (Visit 3)

	Subject	Νι	umb	er:	
1	00-001	-			

#### Fluid consumption report: Month 6

You should decide when to start completing the diary on three consecutive days for this month: on Friday or on Saturday. Depending on your choice, you will complete it on: (please tick the corresponding box below)

Friday - Saturday - Sunday

OR on

Saturday - Sunday - Monday

Date (DD/MM/YYYY): |\_\_|\_|/|\_\_|/|\_\_|

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, _ L
1 After wake up, Before breakfast			_,L
			_, L
			_, _ L
2 During breakfast			_, _ L
			_, _ L



Month 6 (Visit 3)

_			
			_, _ L
3 Between breakfast and lunch			_, _ L
			_, _ L
			_, _ L
4 During lunch			_, _ L
			_, _ L
			_, _ L
5 Between lunch and dinner	1		_, _ L
			_, _ L
6 During dinner	1		_, _ L
			_, _ L
			_, _ L
			_, _ L
7 After dinner			_, _ L
			_, _ L
			_,L
8 During the night			_,L
			_,L



Month 6 (Visit 3)

Subject Number:								
1	00-001-							

Date (DD/MM/YYYY):  _	_ _	/	<u></u>	/ _	_ _	<u> </u>		ı
-----------------------	-----	---	---------	-----	-----	----------	--	---

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, L
1 After wake up, Before breakfast			_, L
	-		_, L
			_, _ L
2 During breakfast			_, _ L
			_, _ L
			_,L
3 Between breakfast and lunch			L
			_, _ L



Month 6 (Visit 3)

			_,L
4 During lunch		-	_, L
		-	_, L
			_, L
5 Between lunch and dinner		-	_, L
			_, L
		-	_, L
6 During dinner		-	_, L
			_, L
	_		_, L
7 After dinner	_		_, L
			_,L
			_,L
8 During the night			_, _ L
			_,L



Month 6 (Visit 3)

Subject Number:						
1	0 0 - 0 0 1 -    _	l				

Date (DD/MM/YYYY):  _	_ _	//	/		_  _
-----------------------	-----	----	---	--	------

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, L
1 After wake up, Before breakfast			_, L
			_, L
			_, L
2 During breakfast			_, L
			_, L
			_,L
3 Between breakfast and lunch			_, L
			_, L



Month 6 (Visit 3)

Subject Number:								
1	00-001-	<u> </u>						

	 	_, _ L
4 During lunch	 	_, _ L
	 	_, L
	 -	_, L
5 Between lunch and dinner	 -	_, L
	 -	_, L
	 	_, _ L
6 During dinner	 	_, L
	 	_, L
	 	_, L
7 After dinner	 	_, L
	 	_, L
	 	_, _ L
8 During the night	 	_, _ L
	 	_,L

# **N**OTES

Have you undergo	here as follows:	· ·	ĺ	•	

© 2018 Hooton TM et al. JAMA Intern Med.

DANON RESEARC	E CH JIEL CARASSO		U369 DRACYST		Month 6 (Visit 3)	1 0	Subject Numbe 0 - 0 0 1 -	er: 
			edication (incress, please s				taken for treatmeng table:	ent of
	Medicat	ion	Start of administration	on	End of administra	tion	Dose/Frequency	
							l site by courier usi nvenient for you	
			Validated I	by t	he investig	ator		
Signa	ture						Date	
(j	ustify an <u></u>	y correc	ction performe	ed (	during the r	eviev	v of the document	:)

Month 6

NU369

DANONE RESEARCH



Month 7

Subject Number:	
100-001-	

# Fluid consumption report: Month 7

You	should	decide	when	to	start	completing	the	diary	on	three
cons	ecutive	days for	this m	ontl	n: on	Friday or o	n Satu	ırday. 🛚	Depe	ending
	our choi be <i>low)</i>	ce, you	will cor	nple	ete it (	on: (please	tick th	ne corr	espo	onding

Date (DD/MM/YYYY):   _ /  / _ _	
□ Saturday – Sunday - Monday	
OR on	
□ Friday – Saturday - Sunday	
box below)	

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, L
1 After wake up, Before breakfast			_,L
			_,L
			_, L
2 During breakfast			_, L
			_, _ L



Month 7

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
			_, L
3 Between breakfast and lunch			_, L
			_, _ L
			_, _ L
4 During lunch			_, _ L
			_, _ L
5 Between lunch and dinner			_, _ L
			_, _ L
			_, _ L
			_, _ L
6 During dinner			_, L
			_, L
			_, L
7 After dinner			_, L
			_, L
			_, _ L
8 During the night			_, _ L
			_, L



Month 7

Date (DD/MM/YYYY):  _	_ _	//	/		_  _
-----------------------	-----	----	---	--	------

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
1 After wake up, Before breakfast			_, L
			_, L
	-		_, L
			_, _ L
2 During breakfast			_, _ L
			_, _ L
			_,L
3 Between breakfast and lunch			L
			_, _ L



# Month 7

4 During lunch			_, _ L
			_, L
	_		_, _ L
			_, _ L
5 Between lunch and dinner			_, _ L
			_, _ L
			_, _ L
6 During dinner			_, _ L
			_, _ L
			_, _ L
7 After dinner			_, _ L
			_, _ L
			_, _ L
8 During the night			_, _ L
			_,L



Month 7

Subject Number:								
100-001-								

Date (DD/MM/YYYY):  _	/	<u> </u>	/	_	.
-----------------------	---	----------	---	---	---

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
1 After wake up, Before breakfast			_, _ L
			_, L
			_, _ L
			_, _ L
2 During breakfast			_, _ L
			_,L
			_,L
3 Between breakfast and lunch			_, _ L
			_, _ L



Month 7

Subject Number: 1 0 0 - 0 0 1 - |\_\_|\_\_|

4 During lunch	1		_, _ L
		-	_, _ L
		-	_, _ L
		-	_, _ L
5 Between lunch and dinner		-	_, _ L
		-	_, _ L
6 During dinner			_, _ L
	-		_,L
	-		_,L
			_, _ L
7 After dinner			_, _ L
			_, _ L
			_, _ L
8 During the night			_, _ L
			_, _ L

# **NOTES**

Have you undergone an adverse event during this month? If yes, please describe it briefly here as follows:	

The state of the s		NU369 YDRACYST Mont		onth 7		Subject Number: 0 - 0 0 1 -		
			edication (incres, please s				taken for treatme	ent of
an auv	Medicati		Start of administration		End of adminis		Dose/Frequency	
							site by courier usi nvenient for you	
			Validated l	by t	he inves	stigator		
Signa	ture						Date	
(justify any correction performed during the review of the document)								

1

NU369



Month 8

Subject Number:	
100-001-  _	

# Fluid consumption report: Month 8

You	should	decide	when	to	start	completing	the	diary	on	three
cons	ecutive	days for	this m	ontl	n: on	Friday or on	Satu	ırday. 🛚	Depe	nding
on ye	our choi	ce, you	will cor	nple	ete it o	on: (please t	ick th	e corr	espo	nding
box l	below)			-					-	
	,									

box below)
□ Friday – Saturday - Sunday
OR on
□ Saturday – Sunday - Monday
Date (DD/MM/YYYY):   _ / _ _ / _ _

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, _ L
1 After wake up, Before breakfast			_, _ L
			_, _ L
			_, _ L
2 During breakfast			_, _ L
			L



Month 8

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
			_, _ L
3 Between breakfast and lunch			_, _ L
			_, _ L
			_, _ L
4 During lunch			_, _ L
			_, _ L
5 Between lunch and dinner			_, _ L
			_, _ L
			_, _ L
			_, L
6 During dinner			_, L
			_, L
			_, L
7 After dinner			_, L
			_, _ L
			_, _ L
8 During the night			_, _ L
			_, _ L



Month 8

	Subject Number:	
1	0 0 - 0 0 1 -	

Date (DD/MM/YYYY):  _	_ _	/		′I				ı
-----------------------	-----	---	--	----	--	--	--	---

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, L
1 After wake up, Before breakfast			_, L
			_, L
			_, L
2 During breakfast			_, L
			_, L
			_, L
3 Between breakfast and lunch			_, L
			_, _ L



Month 8

			_, _ L
4 During lunch			_, L
	_		_, _ L
			_, _ L
5 Between lunch and dinner			_, _ L
			_, _ L
6 During dinner			_, _ L
			_, _ L
			_, _ L
			_, _ L
7 After dinner			_, _ L
			_, _ L
			_, _ L
8 During the night			_, _ L
			_,L



Month 8

Subject Number:	
100-001-  _	_

Date (DD/MM/YYYY):  _	/	<u> </u>	/	_	.
-----------------------	---	----------	---	---	---

	See A	See B	See C	
	Type of drink	Drink package	Amount of drank drink	
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)	
1 After wake up, Before breakfast			_, L	
			_, L	
			_, _ L	
2 During breakfast			_, _ L	
			_, L	
			L	
3 Between breakfast and lunch			_,L	
			_,L	
			_,L	



Month 8

Subject Number: 1 0 0 - 0 0 1 - |\_\_|\_\_|

4 During lunch		-	_, L
	-	-	_, L
	-	-	_, L
5 Between lunch and dinner		-	_, L
		-	_, L
			_, L
6 During dinner		-	_, L
		-	_, L
		-	_, L
7 After dinner			_, L
			_, L
			_, L
8 During the night			_,L
			_, L
			_, _ L

# **N**OTES

Have you undergone an adverse event during this month? If yes, please describe it briefly here as follows:										

© 2018 Hooton TM et al. JAMA Intern Med.

DANONE RESEARCH CENTRE DANIEL CARASSO	NU369 S_HYDRACYST	Month 8	Subject Number: 1 0 0 - 0 0 1 -
	n any medication (inent)? If yes, please s		ations taken for treatment of ollowing table:
Medicat	tion Start of administration	End of administra	tion Dose/Frequency
Remember to s	send back the diary a ope <b>or to give it per</b>	at the investiga	ating site by courier using the re convenient for you
	Validated	by the investig	ator
Signature			Date
(justify an	y correction perform	ed during the r	review of the document)



Month 9

Subject Number:	
100-001-  _	

# Fluid consumption report: Month 9

You	should	decide	when	to	start	completing	the	diary	on	three
cons	ecutive	days for	this m	ontl	h: on	Friday or on	Satu	ırday. 🛚	Depe	nding
on y	our choi	ce, you	will cor	nple	ete it d	on: (please t	ick th	e corr	espo	nding
box	below)									
	•									

Date (DD/MM/YYYY):   _ /  /  /
□ Saturday – Sunday - Monday
OR on
□ Friday – Saturday - Sunday
box below)

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, _ L
1 After wake up, Before breakfast			_, L
			_, L
			_, L
2 During breakfast			_, _ L
			_, _ L



Month 9

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
			_, _ L
3 Between breakfast and lunch			_,L
			_,L
			_, L
4 During lunch			_,L
			_,L
			_, L
5 Between lunch and dinner			_, L
			_, L
			_, _ L
6 During dinner			_, _ L
			_, L
			_, _ L
7 After dinner			_, _ L
			_, L
			_, _ L
8 During the night			_,L
			_, _ L



Month 9

	Subject N	Numb	er:	
1	00-001	-		

Date (DD/MM/YYYY):  _	_ _	/		′I				ı
-----------------------	-----	---	--	----	--	--	--	---

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, L
1 After wake up, Before breakfast			_, L
			_,L
			_,L
2 During breakfast			_, L
			_,L
			_, L
3 Between breakfast and lunch			_, _ L
			_, _ L



Month 9

	 	_, L
4 During lunch	 -	_, L
	 -	_, L
	 	_, L
5 Between lunch and dinner	 	_, L
	 	_, _ L
	 	_, _ L
6 During dinner	 	_, _ L
	 	_, _ L
	 	_, _ L
7 After dinner	 	_, _ L
	 	_, _ L
	 	_, _ L
8 During the night	 	_, _ L
	 	_,L



Month 9

Subject Numb	er:
100-001-	

Date (DD/MM/YYYY):   _	_ / _	_	/			
------------------------	-------	---	---	--	--	--

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, L
1 After wake up, Before breakfast			_, L
			_,L
			_,L
2 During breakfast			_, L
			_,L
			_, L
3 Between breakfast and lunch			_, _ L
			_, _ L



Month 9

Subject Number: 1 0 0 - 0 0 1 - |\_\_|\_\_|\_\_

			_, _ L
4 During lunch			_, _ L
			_, L
		-	_, _ L
5 Between lunch and dinner			_, L
	-		_, _ L
	-		_, _ L
6 During dinner			_, _ L
			_, _ L
			_, _ L
7 After dinner			_, _ L
			_, _ L
			_, _ L
8 During the night			_, _ L
			_, _ L

# **N**OTES

Have you undergo	here as follows:	· ·	ĺ	•	

© 2018 Hooton TM et al. JAMA Intern Med.

DANON RESEAR CENTRE DAN	E S_I CH S_I	NU369 HYDRACYST	M	lonth 9	10	Subject Numbe 0 - 0 0 1 -	r: _
		medication (ind If yes, please s Start of administratio	pec		followir	taken for treatmong table:  Dose/Frequency	ent of
						site by courier usi	
Signa	ture	Validated I	by tl	he investi	gator	Date	
(j	ustify any cor	rection performo	ed d	during the	review	v of the documen	t)

NU369



Month 10

Subject	Number:
100-001	-   _

# Fluid consumption report: Month 10

You	should	decide	when	to	start	completing	the	diary	on	three
cons	ecutive	days for	this m	ontl	n: on	Friday or or	ı Satu	ırday.	Depe	ending
on ye	our choi	ce, you v	will cor	mple	ete it	on: <i>(please</i> :	tick th	ne corr	espo	onding
box l	below)									

•						
□ Friday – Saturday - Sunday						
OR on						
□ Saturday – Sunday - Monday						
Date (DD/MM/YYYY): I	1/1	ı	1/1	ı	1	

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, _ L
1 After wake up, Before breakfast			_, _ L
			_, _ L
			_,L
2 During breakfast			_, _ L
			L



Month 10

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
			_, _ L
3 Between breakfast and lunch			_, _ L
			_, _ L
			_, _ L
4 During lunch			_, _ L
			_, _ L
			_, _ L
5 Between lunch and dinner			_,L
			_, L
			_, L
6 During dinner			_, L
			_, L
			_,L
7 After dinner			_,L
			_, L
			_, L
8 During the night			_, L
			_, _ L



Month 10

Subject Nu	umber:
100-001-	

Date (DD/MM/YYYY):  _	_ _	/		′I				ı
-----------------------	-----	---	--	----	--	--	--	---

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, _ L
1 After wake up, Before breakfast			_, L
			_, _ L
			_, _ L
2 During breakfast			_, _ L
			_,L
			_,L
3 Between breakfast and lunch			_, _ L
			_, _ L



Month 10

	 	_, L
4 During lunch	 -	_, L
	 	_, L
	 	_, L
5 Between lunch and dinner	 	_, L
	 	_, _ L
	 	_, _ L
6 During dinner	 	_, _ L
	 	_, _ L
	 	_, _ L
7 After dinner	 	_, _ L
	 	_, _ L
	 	_, _ L
8 During the night	 	_, _ L
	 	_,L



Month 10

Subject Number:						
1	0 0 - 0 0 1 -    _					

Date (DD/MM/	/YYYY):	<u>  _</u>	_ /	/	'II		_
--------------	---------	------------	-----	---	-----	--	---

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, _ L
1 After wake up, Before breakfast			_,L
			_, _ L
			_,L
2 During breakfast			_, _ L
			_, _ L
			_, _ L
3 Between breakfast and lunch			_, _ L
			_,L



Month 10

Subject Number: 1 0 0 - 0 0 1 - |\_\_|\_\_|

		-	_, L
4 During lunch	-	-	_, L
	-	-	_, L
		-	_, L
5 Between lunch and dinner		-	_, L
			_, L
		-	_, L
6 During dinner		-	_, L
		-	_, L
			_, L
7 After dinner			_, L
			_, L
8 During the night			_,L
			_, L
			_, _ L

# **N**OTES

Have you undergo	here as follows:	· ·	ĺ	•	

© 2018 Hooton TM et al. JAMA Intern Med.

DANON RESEAR CENTRE DA	NU369 NE S_HYDRACYST DANIEL CARASSO		N	onth 10	1 0	Subject Number 0 - 0 0 1 -	er: 		
	Have you taken any medication (including medications taken for treatment of an adverse event)? If yes, please specify in the following table:								
	Medica	tion	Start of administration	on	End of administra	tion	Dose/Frequency		
							site by courier usi		
			Validated I	by t	he investiga	ator			
Signa	ature						Date		
(	(justify any correction performed during the review of the document)								

1

NU369



Month 11

	Subject No	umbe	er:
1	00-001-		_

# Fluid consumption report: Month 11

You	should	decide	when	to	start	comp	leting	the	diary	on	three
cons	ecutive	days for	this m	onth	n: on	Friday	or on	Satu	rday.	Depe	nding
-	our choi below)	ce, you	will co	mple	te it	on: <i>(pl</i> e	ease ti	ck th	e corr	espo	nding

□ Friday – Saturday - Sunday
OR on
□ Saturday – Sunday - Monday
Date (DD/MM/YYYY):   _ / _ / _ / _

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, _ L
1 After wake up, Before breakfast			_, _ L
			_, _ L
			_, _ L
2 During breakfast			_, _ L
			_, _ L



Month 11

_		
	 	_, _ L
3 Between breakfast and lunch	 	_, _ L
	 	_, _ L
	 -	_, _ L
4 During lunch	 	_, _ L
	 -	_, _ L
	 -	_, _ L
5 Between lunch and dinner	 -	_, _ L
	 	_,L
		_, L
6 During dinner		_, L
		_, L
		_, L
7 After dinner		_, L
	 	_,L
	 	_, _ L
8 During the night	 	_, _ L
	 	_, _ L



Month 11

Subject Number:							
1	00-001-						

Date (DD/MM/YYYY):  _	/	<u> </u>	/	_	.
-----------------------	---	----------	---	---	---

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, L
1 After wake up, Before breakfast		-	_, _ L
			_, _ L
			_, _ L
2 During breakfast			_,L
			_,L
			_,L
3 Between breakfast and lunch			_, _ L
			L



Month 11

	 	_, L
4 During lunch	 -	_, L
	 	_, L
	 	_, L
5 Between lunch and dinner	 	_, L
	 	_, L
	 	_, L
6 During dinner	 	_, L
	 	_,L
	 	_, L
7 After dinner	 	_, L
	 	_, _ L
	 	_, L
8 During the night	 	_, L
	 	_,L



Month 11

Subject Number:							
100-001-	_						

Date (DD/MM/YYYY):  _	/	<u> </u>	/	_	.
-----------------------	---	----------	---	---	---

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, L
1 After wake up, Before breakfast			_, L
			_,L
			_,L
2 During breakfast			_, L
			_,L
			_, L
3 Between breakfast and lunch			_, _ L
			_, _ L



Month 11

Subject Number: 1 0 0 - 0 0 1 - |\_\_|\_\_|

	 	_, _ L
4 During lunch	 	_, _ L
	 	_, _ L
	 	L
5 Between lunch and dinner	 	L
	 	L
6 During dinner	 	L
	 	_,L
	 	_,L
	 	_,L
7 After dinner	 	_,L
	 	_,L
	 	_, _ L
8 During the night	 	_, _ L
	 	_, _ L

# **NOTES**

Have you undergone an adverse event during this month? If yes, please describe it briefly here as follows:							

DANON RESEAR	E CH NIEL CARASSO		U369 DRACYST	Month 11		1 0	Subject Number: 0 - 0 0 1 -		
			edication (incres, please s				taken for treatment	    of	
	Medicati	on	Start of administration	on	End of administrat	tion	Dose/Frequency		
							site by courier using nvenient for you	the	
			Validated t	oy t	he investiga	ator			
Signa	ture						Date		
(j	ustify any	orrec	tion performa	ed o	during the re	eviev	v of the document)		

**Subject Number:** 

NU369



Month 12 (Visit 4)

Subject Number:							
100-0	0 1 -  _	_ _ _					

# Fluid consumption report: Month 12

You	should	decide	when	to s	start	complet	ing the	diary	on	three
cons	ecutive	days for	this me	onth	on F	Friday or	on Satu	ırday. 🛚	Depe	ending
_	our choi <i>below)</i>	ce, you	will con	nplet	e it o	n: (pleas	se tick tl	ne corr	espo	onding

Date (DD/MM/YYYY):   _ / _ _ / _ _
☐ Saturday – Sunday - Monday
OR on
☐ Friday – Saturday - Sunday
box below)

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, _ L
1 After wake up, Before breakfast			_, _ L
			_, _ L
			_, _ L
2 During breakfast			_, _ L
			_, _ L



Month 12 (Visit 4)

_		
	 	_, _ L
3 Between breakfast and lunch	 	_, _ L
	 	_, _ L
	 -	_, _ L
4 During lunch	 	_, _ L
	 -	_, _ L
	 -	_, _ L
5 Between lunch and dinner	 -	_, _ L
	 	_, _ L
		_, L
6 During dinner		_, L
		_, L
		_, L
7 After dinner		_, L
	 	_,L
	 	_, _ L
8 During the night	 	_, _ L
	 	_, _ L



Month 12

	Subject	Νι	ımb	er:	
1 0	0 - 0 0 1	-			

Date (DD/MM/YYYY):  _	/	<u> </u>	/	_	.
-----------------------	---	----------	---	---	---

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, _ L
1 After wake up, Before breakfast			_, L
			_, _ L
			_, _ L
2 During breakfast			_, _ L
			_,L
			_,L
3 Between breakfast and lunch			_, _ L
			_, _ L



Month 12

	 	_, L
4 During lunch	 -	_, L
	 -	_, L
	 	_, L
5 Between lunch and dinner	 	_, L
	 	_, L
	 	_, _ L
6 During dinner	 	_, _ L
	 	_, _ L
	 	_, _ L
7 After dinner	 	_, _ L
	 	_, _ L
	 	_, _ L
8 During the night	 	_, _ L
	 	_,L



Month 12

Subject Nu	umber:
100-001-	

Date (DD/MM/YYYY):  _	_ _	/		′I				ı
-----------------------	-----	---	--	----	--	--	--	---

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, L
1 After wake up, Before breakfast			_, L
	-		_, L
			_,L
2 During breakfast			_,L
			_, _ L
			_,L
3 Between breakfast and lunch			L
			_, _ L



Month 12

Subject Number: 1 0 0 - 0 0 1 - |\_\_|\_\_|\_\_

		-	_, _ L
4 During lunch	-	-	_, _ L
	-	-	_, _ L
		-	_, _ L
5 Between lunch and dinner		-	_, _ L
	-	-	_, _ L
		-	_, _ L
6 During dinner		-	_, _ L
		-	_, _ L
	-		_, L
7 After dinner			_, L
			_, _ L
			_,L
8 During the night			_, _ L
			_, _ L

# **NOTES**

Have you u describe it		uring this n	nonth? If	yes, ple	ase

DANON RESEAR	E CH		U369 DRACYST	Month 12	Subject Number 1 0 0 - 0 0 1 -	
			medication (inclu		tions taken for treatmowing table:	nent of
	Medicat	tion	Start of administration	End of administration	Dose/Frequency	
					ng site by courier usin convenient for you.	
			Validated by t	he investigat	or	
Signa	ture				Date	
(justify any correction performed during the review of the document)						

DANONE RESEARCH
CENTRE DANIEL CARASSO

Month
l

	Subject	Νı	umb	er:	
1	00-001	-			

Fluid	consum	ption	report:	Month	1 1

You	should	decide	when	to	start	compl	eting	the	diary	on	three
cons	ecutive	days for	this m	onth	: on	Friday (	or on	Satu	rday.	Depe	nding
-	our choi below)	ce, you v	will cor	nple	te it	on: <i>(pl</i> e	ase ti	ck th	e corr	espo	nding

	Friday –	Saturday	- Sunday
OI	R on		

Date (DD/MM/YYYY): |\_\_|\_|/|\_|\_|/|\_\_|

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_,L
1 After wake up, Before breakfast			_,L
			_, L
			_, L
2 During breakfast			_, L
			_, _ L



	Мо	nt	h
I			_[

_		
	 	_, _ L
3 Between breakfast and lunch	 	_, _ L
	 	_, _ L
	 -	_, _ L
4 During lunch	 	_, _ L
	 -	_, _ L
	 -	_, _ L
5 Between lunch and dinner	 -	_, _ L
	 	_, _ L
		_, L
6 During dinner		_, L
		_, L
		_, L
7 After dinner		_, L
	 	_,L
	 	_, _ L
8 During the night	 	_, _ L
	 	_, _ L



V	lont	h
<u> </u>	_l_	_

Subject Number:							
1	00	- 0 0	1	-			

Date (DD/MM/YYYY):   _	_ /	<u> </u>		/		<u> </u>	
------------------------	-----	----------	--	---	--	----------	--

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, L
1 After wake up, Before breakfast			_, L
			_, L
			_, L
2 During breakfast			_, L
			_, L
			_,L
3 Between breakfast and lunch			_, L
			_, L



M	lont	h
<u></u>	_l_	_I

	 -	_, L
4 During lunch	 -	_, L
	 	_, L
	 -	_, L
5 Between lunch and dinner	 -	_, L
	 	_,L
	 	_,L
6 During dinner	 	_, _ L
	 	_, L
	 	_, _ L
7After dinner	 -	_, L
	 	_,L
	 	_, L
8 During the night	 	_, L
	 	_, _ L



M	onth	
<u></u>	_l	

Subject Number:							
1	00-001	-					

Date (DD/MM/YYYY):  _	/	<u> </u>	/	_	.
-----------------------	---	----------	---	---	---

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, L
After wake up, Before breakfast			_, L
			_,L
			_,L
2 During breakfast			_, L
			_,L
			_, L
3 Between breakfast and lunch			_, _ L
			_, _ L

DANONE RESEARCH
CENTRE DANIEL CARASSO

M	lont	h
<u></u>	_l_	_I

# Subject Number: 1 0 0 - 0 0 1 - |\_\_|\_\_|\_\_

	 	_, _ L
4 During lunch	 	_, _ L
	 	_, L
	 -	_, L
5 Between lunch and dinner	 	_, L
	 	_, _ L
	 	_, _ L
6 During dinner	 	_, L
	 	_, L
	 	_, L
7 After dinner	 	_, L
	 	_, L
	 	L
8 During the night	 	L
	 	_, _ L

# **NOTES**

Have you undergone an adverse event during this month? If ye describe it briefly here as follows:	

© 2018 Hooton TM et al. JAMA Intern Med.

DANON RESEAR	E S_	NU369 HYDRACYST	Month II_I	Subject Number: 1 0 0 - 0 0 1 -
		y medication (inclu		ations taken for treatment of
	Medication	Start of administration	End of administrat	Dose/Frequency
				ting site by courier using the convenient for you.
Signa	ture	Validat	ed by the ir	ovestigator Date
(j	ustify any cor	rection performed	during the r	eview of the document)

•
DANONE RESEARCH
CENTRE DANIEL CARASSO

Mo	onth
I	<u> </u>

Subject Number:						
1	0 0 - 0	01-	_	_		

Fluid consu	umption	report:	Month	ΙI	

You	should	decide	when	to	start	completing	the	diary	on	three
cons	ecutive	days for	this m	ontl	n: on	Friday or on	Satu	ırday. I	Depe	ending
on y	our choi	ce, you v	will co	mple	ete it o	on: <i>(please t</i>	ick th	ie corr	espo	onding
box l	below)									

□ Friday –	Saturday	- Sunday
------------	----------	----------

OR on

☐ Saturday – Sunday - Monday

Date (DD/MM/YYYY): |\_\_|\_|/|\_\_|/|\_\_|

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, _ L
1 After wake up, Before breakfast			_,L
			_, L
			_, L
2 During breakfast			_, L
			_, _ L



M	lont	h
<u> </u>	_l_	_

_		
	 	_, L
3 Between breakfast and lunch	 	_, L
	 	_, _ L
	 -	_, _ L
4 During lunch	 	_, _ L
	 -	_, _ L
	 -	_, _ L
5 Between lunch and dinner	 -	_, _ L
	 	_, _ L
	 	_, L
6 During dinner		_, L
		_, L
		_, L
7 After dinner		_, L
	 	_,L
	 	_, _ L
8 During the night	 	_, L
	 	_, L



M	onth	
<u></u>	_l	I

Subject Number:							
1	0 0	- 0 (	1 (	-			

Date (DD/MM/YYYY):	_/	<u>                                      </u>	/  _	.	
--------------------	----	---	------	---	--

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, L
1 After wake up, Before breakfast			_, _ L
			_, _ L
			_, _ L
2 During breakfast			_, _ L
			_, _ L
			_, _ L
3 Between breakfast and lunch			_, _ L
			_, _ L
			_, _ L
4 During lunch			_, _ L
			_, _ L



M	lont	h
<u></u>	_l_	_I

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
			_, L
5 Between lunch and dinner			_, L
			_, L
			_, L
6 During dinner			_, L
			_, L
			_, L
7 After dinner			_, L
			_, L
			_, _ L
8 During the night			_, L
			_,L



M	lont	th
<u></u>	_l_	_

Subject Number: 1 0 0 - 0 0 1 - |\_\_|\_\_|

Date (DD/MM/YYYY): |\_\_|\_|/|\_|\_|/|\_\_|

	See A	See B	See C
	Type of drink	Drink package	Amount of drank drink
	Enter the code type of beverage	Enter the code for type of packaging you drunk (mentioned on columns A)	Enter the quantity consumed drink at that time of the day In liters For example: 0.25 L (a glass) 0.33 L (can of Cola) 0.20 L (less than a tea cup)
			_, L
1 After wake up, Before breakfast			_, L
			_, _ L
			_, _ L
2 During breakfast			_, _ L
			_,L
			_,L
3 Between breakfast and lunch			_,L
			_, _ L
			_,L
4 During lunch			_, _ L
			_, _ L

•
DANONE RESEARCH
CENTRE DANIEL CARASSO

Month					
<u> </u>	_l_	_I			

_		
		 _, L
5 Between lunch and dinner	1	 _, _ L
		 _, L
	1	 _, L
6 During dinner		 _, L
	1	 _, L
	1	 _, L
7 After dinner	1	 _, L
	1	 _, L
		 _,L
8 During the night		 _,L
		 _, L



Мо	nth
I	<u> </u>

Subject Number:						
100-00	1	-				

# Notes

Have you undergone an adverse event during this month? If yes, please describe it briefly here as follows:							
Have you taken any medication (including medications taken for treatment of an adverse event)? If yes, please specify in the following table:							
	Medication	Start of administration	End of administration	Dose/Frequency			
Remember to send back the diary at the investigating site, by courier, using the pre-print envelop or to give it personally if more convenient for you.							
	Validated by the investigator						
Signature Date							
(justify any correction performed during the review of the document)							



# eMethods 2. Voiding diary

Subject identification:

100 - 0 0 1 - |\_\_|\_\_|

Subject identification and visit number at each page must be completed by the investigator

Voiding diary – version 3.0, Date: 20/01/2015 © 2018 Hooton TM et al. *JAMA Intern Med.* 



Subject identification: 100 - 0 0 1 -   _
---

#### **GUIDELINES FOR 24 HOURS URINE COLLECTION**

You should collect all excreted urine beginning from the second micturition on the day you start collecting it until the first micturition (inclusive) on the next day after waking up. You should keep in mind that the first micturition on the second day should be collected at the same time when the first micturition on the previous day occurred.

After you have woken up on the day you start 24H urine collecting, please write down the date and time of first micturition. <u>DO NOT INCLUDE THIS MICTURITION</u> in the big container given to you!
Date: Time::
I hereby confirm that this micturition was not included in the container.  up yes  up no (comment):

<u>24H urine collection starts from now on.</u> Write down all moments when you have urinated whereas you should collect <u>all micturitions in the container</u>:

Date	Time	Did you feel a strong urge to go? (yes/no)	Did you have any complaints during voiding? (please describe in brief)

Voiding diary - version 3.0,

Date: 20/01/2015

© 2018 Hooton TM et al. JAMA Intern Med.



Subject identification:				
100 - 0 0 1 -				

After you have woken up on the day you finish 24H urine collecting, please write down the date and time of first micturition and add the urine to the container.. Please remember that the first micturition on the second day should be collected at the same time when the first micturition on the previous day occurred.

# Signature: Date:

(justify any correction performed during the review of the document)

Voiding diary - version 3.0, Date: 20/01/2015 © 2018 Hooton TM et al. JAMA Intern Med.