

Item #	Item Concept	Reference Categories	Reference Categories Link (if applicable)	Recommended Degree of Requirement	Issues with referenced standard terminology
Current Contact Information					
1	GRDR001 Registry Unique Participant ID		GUID Elements Appendix!A1	Required	
2	GRDR002 Participant Identifier Source			Required	
3	GRDR003 Source Registry			Required	
4	GRDR004 Registry Record Date	Date in ISO-8601 format: YYYY-MM-DD	ISO 8601	Required	
5	First Name of Participant GUID		HL7 ST data type	Required	String data type but appropriate HL7 data type available: XPN

6	Last Name of Participant GUID		<u>HL7 ST data type</u>	Required	String data type but appropriate HL7 data type available: XPN
7	Middle Name of Participant GUID		<u>HL7 ST data type</u>	Required	String data type but appropriate HL7 data type available: XPN
8	Participant Street Address		<u>HL7 ST data type</u>	Required	String data type but appropriate HL7 data type available: XAD
9	Participant City		<u>HL7 ST data type</u>	Required	String data type but appropriate HL7 data type available: XAD
10	GRDR005 State of Participant's Residence		<u>Postal service state names and abbreviations</u>	Required	
11	GRDR006 Zip/Postal Code of Participant's Residence		<u>USPS 3-Digit Zip Code Prefix Matrix</u>	Required	Previously recorded all 5 digits
12	GRDR007 Country of Participant's Residence		<u>ISO-3166</u>	Required	
13	Participant Email Address			Required	

14	Participant Primary Telephone Number		<u>HL7 TN data type</u>	Required	TN data type deprecated but appropriate HL7 data type available: XTN
15	Registrar	1-Yes 2-No	<u>LOINC Yes/No</u>	Required	References LOINC code 67791-4, question: Does the patient take any medications? Code used because response is appropriate
16	Name of Registrar		<u>HL7 ST data type</u>	Required	String data type but appropriate HL7 data type available: XPN
17	GRDR008 Record of Self Completion	1 – Yes 2 – No 3 – Refused 4 – Don't know	<u>LOINC Yes/No/Refused/Don't Know</u>	Required	References LOINC code 63513-6, question: Are you covered by health insurance or some other kind of health care plan? Code used
18	GRDR009 Proxy Relationship to Participant	1 - Self 2 - Parent (biologic, adoptive, or step) 3 - Grandparent 4 - Spouse 5 - Aunt/Uncle 6 - Brother/Sister 7 - Other relative 8 - Legal guardian 9 - Foster parent 10 - Medical caregiver 11 - Other non-relative 12 - Refused 13 - Don't know		Required	
19	Consent	1 - Yes 2 - No	<u>LOINC Yes/No</u>	Required	References LOINC code 67791-4, question: Does the patient take any medications? Code used because response is appropriate
20	Assent	1 - Yes 2 - No 0 - Participant gives own consent -1 - Participant is unable to assent	<u>LOINC Yes/No</u>	Required	References LOINC code 67791-4, question: Does the patient take any medications? Code used because response is appropriate
Socio-Demographic					

21	GRDR010 Participant Year of Birth GUID		<u>ISO 8601</u>	Required	Previously recorded full date of birth
22	GRDR011 Vital Status	1 – Yes 2 – No 3 – Refused 4 – Don't know	<u>LOINC</u> <u>Yes/No/Refused/Don't</u> <u>Know</u>	Required	References LOINC code 63513-6, question: Are you covered by health insurance or some other kind of health care plan? Code used
23	GRDR012 Year of Death		<u>ISO 8601</u>	Required	previously recorded full date of death
24	GRDR013 Sex of Participant GUID	1 - Male 2 - Female 3 - Other 4 - Transsexual 5 – Unknown	<u>LOINC/NAACCR extended</u> <u>sex</u>	Required	
25	GRDR014 Race of Participant	1 – American Indian or Alaska Native 2 – Asian 3 – Asian Indian 4 – Chinese 5 – Filipino 6 – Japanese 7 – Korean 8 – Vietnamese 9 – Other Asian 10 – Black or African American 11 – Native Hawaiian or Other Pacific Islander 12 – Native Hawaiian 13 – Guamanian 14 – Chamorro 15 – Samoan 16 – Other Pacific Islander 17 – <u>White</u>	<u>LOINC Extended Race</u>	Required	Most studies still use OMB standard for race, which contains broader categories
26	GRDR015 Ethnicity of Participant	1 – Hispanic or Latino 2 – Central American 3 – Cuban 4 – Dominican (Republic) 5 – Mexican 6 – Puerto Rican 7 – South American 8 – Other Latin American 9 – Other Hispanic/Latino/Spanish 10 – Non-Hispanic or Latino	<u>LOINC Ethnicity</u>	Required	Most studies still use OMB standard for ethnicity, which contains broader categories

27	Nationality		<u>ISO 3166-1alpha-2 code</u>	Optional	links to ISO3166-1 alpha 3 code
28	GRDR016 Country of Birth		<u>ISO-3166</u>	Required	
29	GRDR017 State or Province of Birth		<u>Postal service state names and abbreviations</u>	Optional	
30	City, Town or Village of Birth GUID		<u>HL7 ST data type</u>	Required	String data type but appropriate HL7 data type available: XAD
31	GRDR018 Health Insurance Coverage	1 – Yes 2 – No 3 – Refused 4 – Don't know	<u>ISO 8601</u>	Optional	References LOINC code 63513-6, question: Are you covered by health insurance or some other kind of health care plan? Code used
32	GRDR019 Health Insurance Type	1 – Private health insurance 2 – Medicare 3 – Medi-gap 4 – Medicaid 5 – SCHIP (Children's Health Insurance Program) 6 – Military health care (Tricare/VA, Champ-VA) 7 – Indian health service 8 – State-sponsored health plan 9 – Other government program 10 – Single service plan (e.g. dental)	<u>LOINC Insurance</u>	Optional	

33	GRDR020 Grade Level	1 - No schooling 2 - Preschool or nursery school 3 - Kindergarten 4 - 1st Grade 5 - 2nd Grade 6 - 3rd Grade 7 - 4th Grade 8 - 5th Grade 9 - 6th Grade 10 - 7th Grade 11 - 8th Grade 12 - 9th Grade 13 - 10th Grade 14 - 11th Grade 15 - 12th Grade 16 - GED 17 - College 30 - Don't Know		Optional
34	GRDR021 Educational Attainment	1 - Eighth grade or less 2 - More than eighth grade, but did not graduate from high school 3 - Went to a business, trade, or vocational school instead of high school 4 - High school graduate 5 - Completed a GED 6 - Went to a business, trade, or vocational school after high school 7 - Went to college, but did not graduate 8 - Graduated from a college or university 9 - Professional training beyond a four-year college or university	<u>LOINC level of education</u>	Optional

35	GRDR022 Maternal Educational Attainment	<p>1 – Eighth grade or less 2 – More than eighth grade, but did not graduate from high school 3 – Went to a business, trade, or vocational school instead of high school 4 – High school graduate 5 – Completed a GED 6 – Went to a business, trade, or vocational school after high school 7 – Went to college, but did not graduate 8 – Graduated from a college or university 9 – Professional training beyond a</p>	<u>LOINC level of education</u>	Optional	Small change to output from version 1
36	GRDR023 Paternal Educational Attainment	<p>1 – Eighth grade or less 2 – More than eighth grade, but did not graduate from high school 3 – Went to a business, trade, or vocational school instead of high school 4 – High school graduate 5 – Completed a GED 6 – Went to a business, trade, or vocational school after high school 7 – Went to college, but did not graduate 8 – Graduated from a college or university 9 – Professional training beyond a</p>	<u>LOINC level of education</u>	Optional	Small change to output from version 1

37	GRDR024 Family Income	1 - Less than \$10000 (USD) 2 - \$10000 - \$14999 3 - \$15000 - \$19999 4 - \$20000 - \$24999 5 - \$25000 - \$29999 6 - \$30000 - \$34999 7 - \$35000 - \$39999 8 - \$40000 - \$44999 9 - \$45000 - \$49999 10 - \$50000 - \$54999 11 - \$55000 - \$59999 12 - \$60000 - \$74999 13 - \$75000 - \$84999 14 - \$85000 - \$99999 15 - \$100000 - \$149999 16 - \$150000 - \$199999 17 - \$200000 -		Optional
38	GRDR025 Household Size			Optional
39	Number in Group House	0 - Participant does not live in a group house 2 - 2 3 - 3 4 - 4 5 - 5 6 - 6 7 - 7 8 - 8 9 - 9 10 - 10 11 - 11 12 - 12 13 - 13 14 - 14 15 - 15 16 - 16 17 - 17 18 - 18 19 - 19 20 - 20 # Entered - Other- enter number		Optional
Diagnosis				

40	GRDR026 Rare Disease Diagnosis	Registry responses are mapped to SNOMED-CT concepts, and the GRDR stores the SNOMED-CT identifiers.	<u>SNOMED-CT</u>	Required
41	GRDR027 Age at Diagnosis	-2 - Prenatal -1 - At birth 0 - Less than 1 year 1 - 89 age in years 90 - 90+ years -3 - Age of diagnosis unknown		Required
42	GRDR028 Age of Symptom Onset	-2 - Prenatal -1 - At birth 0 - Less than 1 year 1 - 89 age in years 90 - 90+ years -4 - Participant never experienced any symptoms -3 - Age of onset unknown		Required
43	GRDR029 Rare Disease Diagnostic Testing	Registry responses are mapped to LOINC IDs, and the GRDR stores the LOINC identifiers. 0 - None	<u>LOINC</u>	Required

Family History

44	GRDR030 Rare Disease Family History	0 - None 1 - Daughter 2 - Granddaughter 3 - Grandson 4 - Half-brother 5 - Half-sister 6 - Maternal Aunt 7 - Maternal Cousin 8 - Maternal Grandfather 9 - Maternal Grandmother 10 - Maternal Uncle 11 - Brother 12 - Father 13 - Mother 14 - Sister 15 - Nephew 16 - Niece 17 - Paternal Aunt 18 - Paternal Cousin 19 - Paternal Grandfather 20 - Paternal Grandmother 21 - Paternal Uncle 22 - Son	<u>LOINC Family Relationships</u>	Required	Additional categories added
45	GRDR031 Birth Weight	The GRDR will record 2 values: 1. The weight (with units) reported by the registry 2. The weight in grams		Optional	
46	GRDR032 Participant Term Delivery	1 - Yes 2 - No 3 - Refused 4 - Don't know	<u>LOINC Yes/No/Refused/Don't Know</u>	Optional	References LOINC code 63513-6, question: Are you covered by health insurance or some other kind of health care plan? Code used

47	GRDR033 Participant Premature Gestational Age at Birth	-2 - 2 weeks late -1 - 1 week late 0 - On time 1 - 1 week premature 2 - 2 weeks premature 3 - 3 weeks premature 4 - 4 weeks premature 5 - 5 weeks premature 6 - 6 weeks premature 7 - 7 weeks premature 8 - 8 weeks premature 9 - 9 weeks premature 10 - 10 weeks premature 11 - 11 weeks premature 12 - 12 weeks premature 13 - 13 weeks		Optional
48	Number of Pregnancies			Optional
49	Number of Live Births			Optional
50	Number of Living Children			Optional
Anthropometric				
51	GRDR034 Participant Weight	The GRDR will record 2 values: 1. The weight (with units) reported by the registry 2. The weight in grams		Optional

52	GRDR035 Participant Age for Weight	Year + partial year in increments of 0.25	<u>Age to Height</u> <u>Appendix!A1</u>	Optional	
53	GRDR036 Participant Height	The GRDR will record 2 values: 1. The height (with units) reported by the registry 2. The height in centimeters		Optional	
54	GRDR037 Participant Age for Height	Year + partial year in increments of 0.25	<u>Age to Height</u> <u>Appendix!A1</u>	Optional	
Patient Reported Outcome					
55	General Health	1- Excellent 2- Very good 3- Good 4- Fair 5- Poor	<u>PROMIS SF v1.0 -</u> <u>Global Health:</u>	Optional	LOINC references PROMIS. The response variables are different.
56	Physical Functioning	1- Not at all 2- Very little 3- Somewhat 4- Quite a lot 5- Cannot do	<u>PROMIS SF v1.0 10a</u> <u>- Physical</u>	Optional	LOINC references PROMIS. The response variables are different.
57	Pain	1- Not at all 2- A little bit 3- Somewhat 4- Quite a bit 5- Very much	<u>PROMIS SF v1.0 -</u> <u>Fatigue 6b:</u>	Optional	LOINC references PROMIS. The response variables are different.
58	Fatigue	1- Never 2- Rarely 3- Sometimes 4- Often 5- Always	<u>PROMIS SF v1.0 -</u> <u>Fatigue 7a:</u>	Optional	LOINC references PROMIS. The response variables are different.
59	Depression	1- Never 2- Rarely 3- Sometimes 4- Often 5- Always	<u>PROMIS SF v1.0 -</u> <u>Depression 8b:</u>	Optional	LOINC references PROMIS. The response variables are different.

Medications, Devices and Health Services

60	GRDR038 Current Medications	Registry responses are mapped to RxNorm identifiers specifying the active ingredient(s) and route of administration	<u>RxNorm</u>	Optional
61	GRDR039 Medical Foods/Special Diet	Registry responses are mapped to NDF-RT identifiers. 0 - None	<u>National Drug File - Reference Terminology</u>	Optional
62	GRDR040 Previous Surgeries	Registry responses are mapped to SNOMED-CT surgery concepts, and the GRDR stores the SNOMED-CT identifiers.	<u>SNOMED-CT</u>	Optional
63	Participant Hospitalization	1- Yes 2- No 3- Refused 4- Don't know		Optional
64	GRDR041 Participant Hospitalization Count			Optional
65	GRDR042 Participant Assistive Device	Registry responses are mapped to UMDNS identifiers 0 - None	<u>Universal Medical Device Nomenclature System</u>	Optional

Is this suppose to reference: LOINC code 63513-6, question: Are you covered by health insurance or some other kind of health care plan?

Clinical Research Participation & Biospecimens

66	GRDR043 Participant Previous Trial Participation	1- Yes 2 -No 3- Refused 4- Don't know	<u>0</u>	Required
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References LOINC code 63513-6, question: Are you covered by health insurance or some other kind of health care plan?
Code used

67	GRDR044 Participant Current Trial Participation	1 – Yes 2 – No 3 – Refused 4 – Don't know	<u>0</u>	Required
68	GRDR045 Participant Future Trial Participation	1 – Yes 2 – No 3 – Refused 4 – Don't know	<u>0</u>	Required
69	GRDR046 Participant Future Biospecimen Donation	1 – Yes 2 – No 3 – Refused 4 – Don't know	<u>0</u>	Required
70	GRDR047 Participant Existing Biospecimen	1 – Yes 2 – No 3 – Refused 4 – Don't know	<u>0</u>	Required
71	GRDR048 Participant Existing Biospecimen Type	1 - Blood 2 - Saliva/Cheek Swab 3 - Urine 4 - Other bodily fluid 5 - Tissue		Required
72	Location of biospecimen donation		<u>HL7 TX data type</u>	Optional
Contact and Communication Preferences				
73	Participant Preferred Method of Communication	1- Sign language 2- Spoken language 3- Written language	<u>Http://www.hl7.org/</u>	Required
74	Participant Preferred Contact	1- Email 2- Mail 3- Phone	<u>Http://www.hl7.org/</u>	Required

References LOINC code 63513-6, question: Are you covered by health insurance or some other kind of health care plan?
Code used

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Code used

Administrative

75	GRDR049 GRDR ID		<u>GUID Elements</u> <u>Appendix IA1</u>	
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