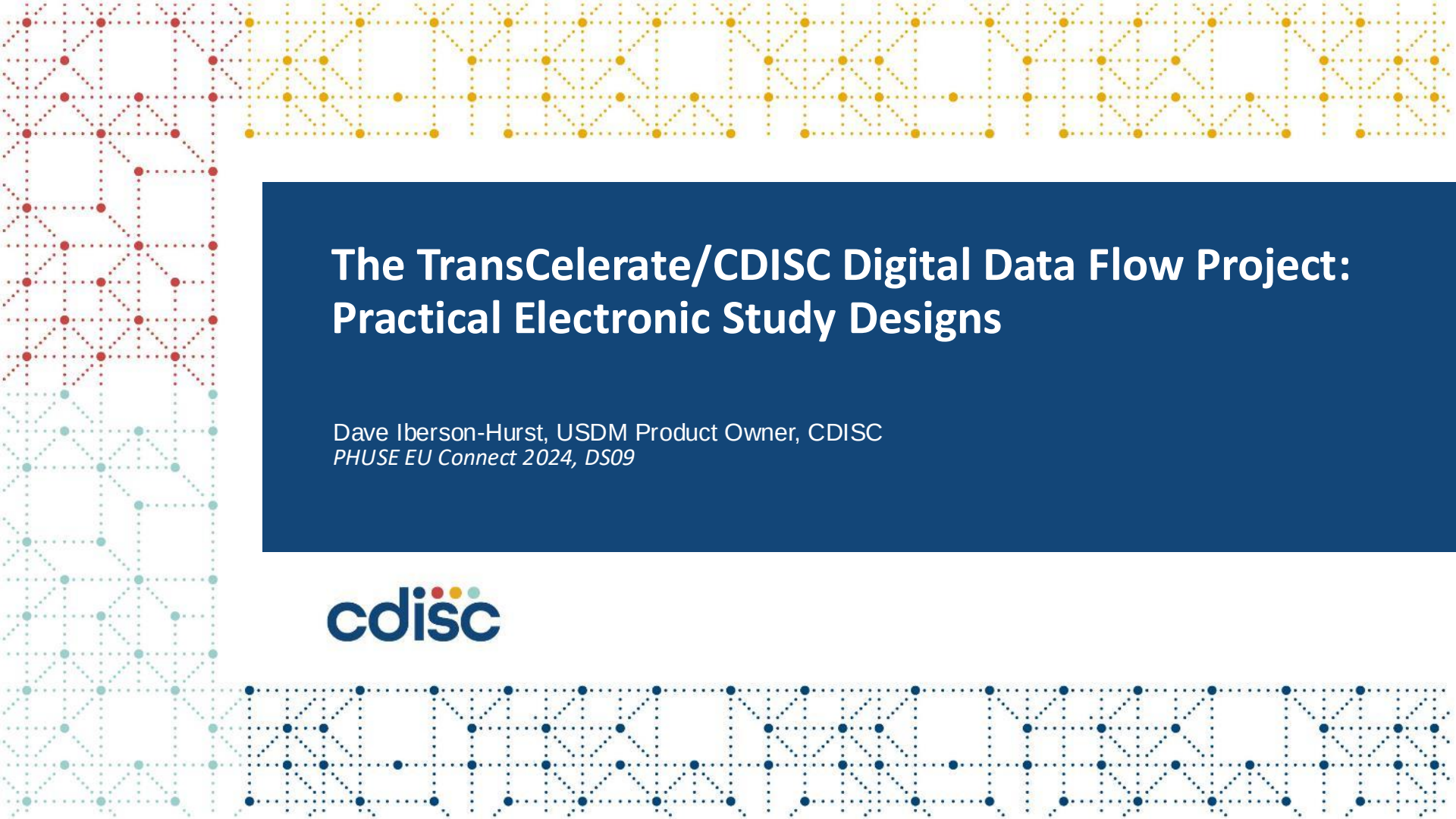
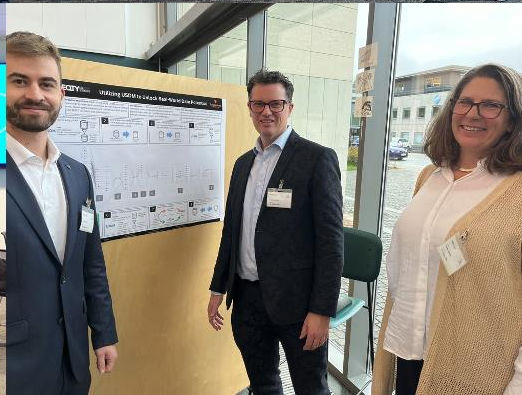
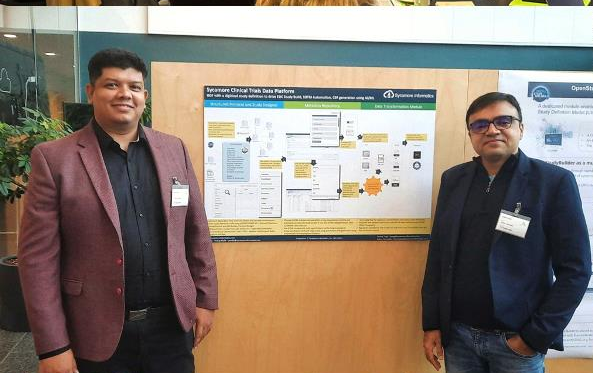




The TransCelerate/CDISC Digital Data Flow Project: Practical Electronic Study Designs

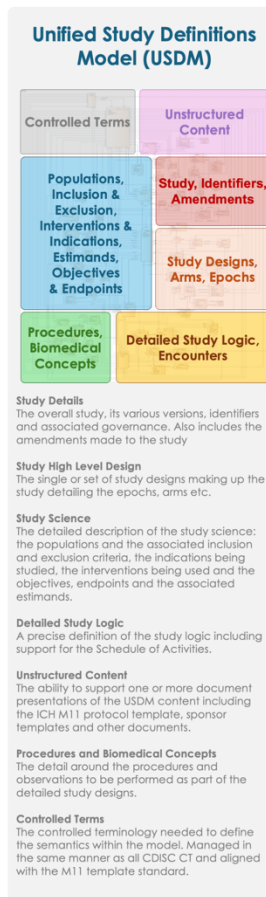
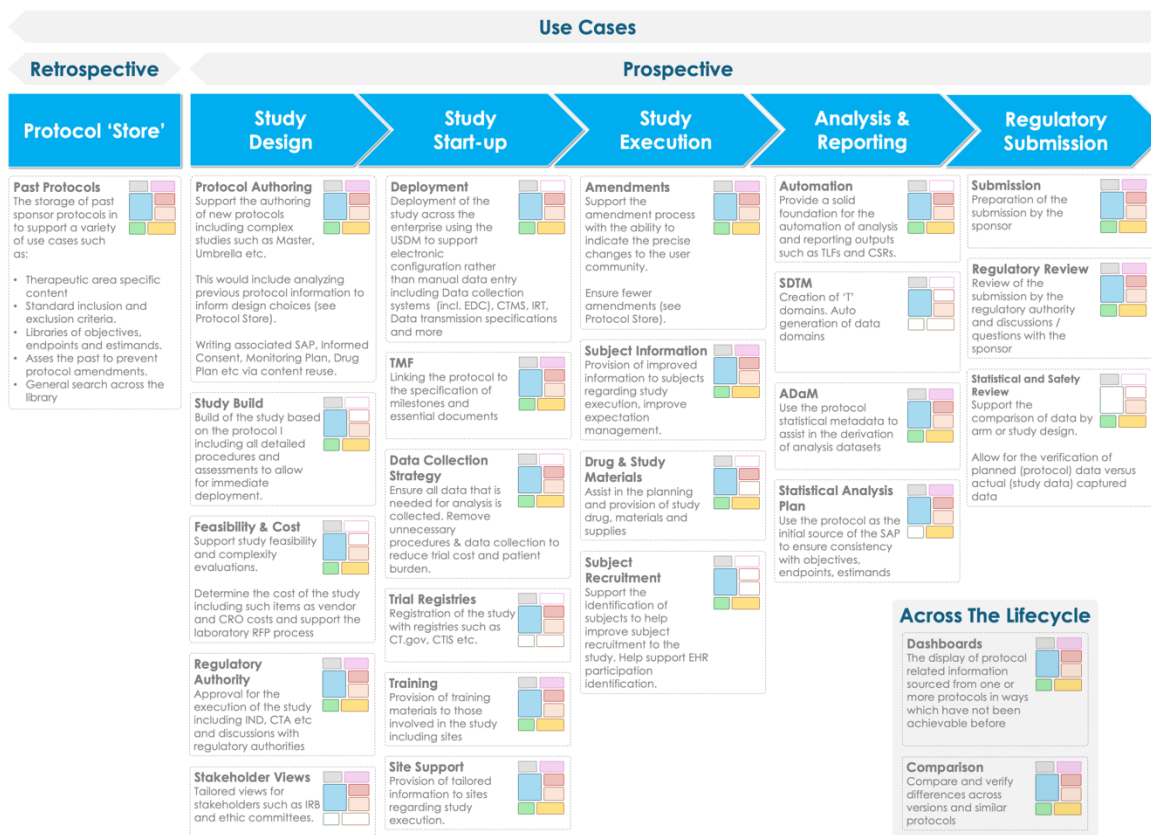
Dave Iberson-Hurst, USDM Product Owner, CDISC
PHUSE EU Connect 2024, DS09





USDM in Action

Use Cases Supporting the DDF Vision



NOTE: The use cases presented are illustrative and the list is not intended to be exhaustive.



“DDF in Action”: Sponsor Presentations

- **Eli Lilly:**
The Digital Schedule of Activities
- **Roche:**
How can we unlock the power of data and technology to transform study design and protocol generation?
- **Novo Nordisk:**
Adoption of Digital Data Flow

Stakeholder Views
Tailored views for stakeholders such as IRB and ethic committees.

Site Support
Provision of tailored information to sites regarding study execution.

Comparison
Compare and verify differences across versions and similar protocols

Procedures and Biomedical Concepts
The detail around the procedures and observations to be performed as part of the detailed study designs.

Controlled Terms
The controlled terminology needed to define the semantics within the model. Managed in the same manner as all CDISC CT and aligned with the M11 template standard.

NOTE: The use cases presented are illustrative and the list is not intended to be exhaustive.

“DDF in Action” Posters

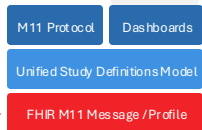
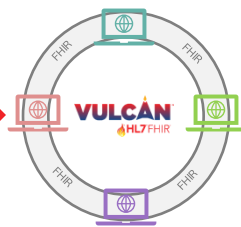
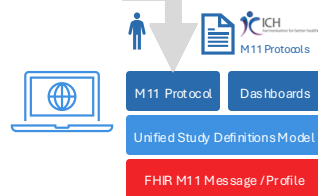
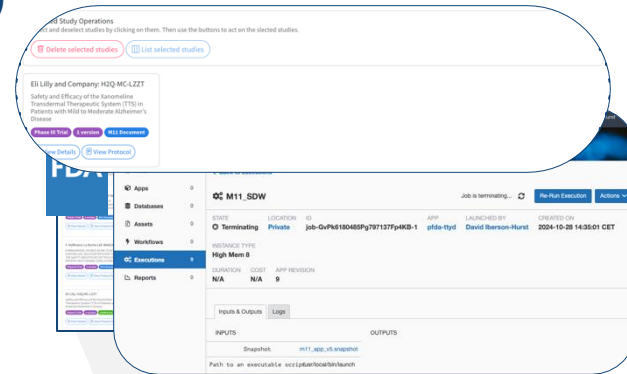
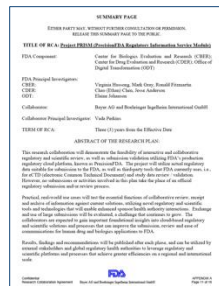
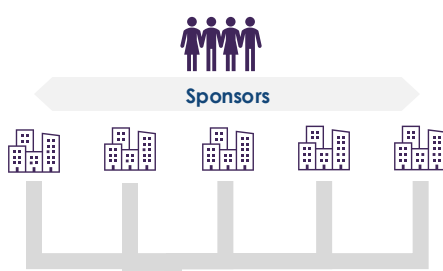
Novo Nordisk: Copenhagen

- **data4knowledge:**
One model USDM at the Center
- **EQTY Lifesciences and ClinLine:**
Utilizing USDM to unlock real world data potential
- **Novo Nordisk:**
OpenStudyBuilder: A USDM compatible SDR solution
- **Nurocor:**
Nurocor Clinical Platform: Making DDF a reality today
- **Sycamore Informatics:**
Sycamore Clinical Trials Data Platform
- **TransCelerate:**
Study Definitions Repository (SDR)

J&J: New Jersey

- **EZ Research Solutions:**
The power of seamless innovation (USDM, AI, Automation and Collaboration)
- **NNIT:**
FHIR and USDM in action
- **Novo Nordisk:**
OpenStudyBuilder: A USDM compatible SDR solution
- **Nurocor:**
Nurocor Clinical Platform: Making DDF a reality today
- **Tata Consultancy Services (TCS):**
AI Enabled Trial Design Dataset Automation
- **Sycamore Informatics:**
Sycamore Clinical Trials Data Platform
- **PFMD and CTDN:**
Applying USDM resources to Protocol Eligibility Criteria also supports clinical trial matching, patient and site enrollment and inclusiveness use cases
- **Contentrules and Futurpositif:**
USDM enables content reuse from the study protocol
- **TransCelerate:**
Study Definitions Repository (SDR)

PRISM M11 Use Case (PrecisionFDA Regulatory Information Service Module)



Sponsor

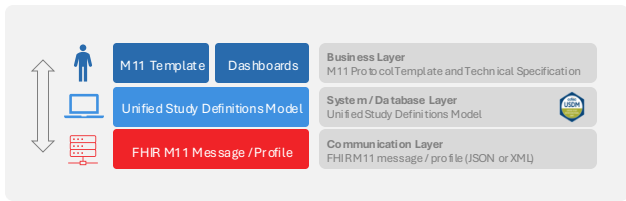
1

- M11 '.docx' → USDM → FHIR
- Try and make it easy, "a few clicks"

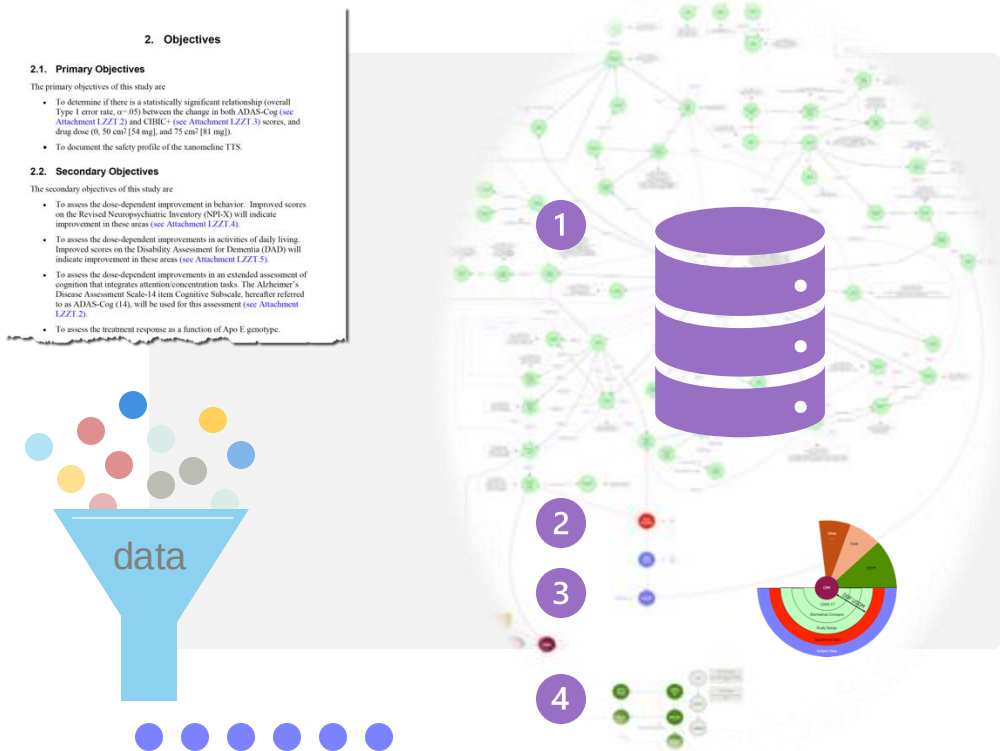
FDA

2

- FHIR → USDM → M11 Presentation
- Dashboards, what is possible?



- To assess the dose-dependent improvement in behavior. Improved scores on the Revised Neuropsychiatric Inventory (NPI-X) will indicate improvement in these areas (see Attachment LZZT.4).
- To assess the dose-dependent improvements in activities of daily living. Improved scores on the Disability Assessment for Dementia (DAD) will indicate improvement in these areas (see Attachment LZZT.5).
- To assess the dose-dependent improvements in an extended assessment of cognition that integrates attention/concentration tasks. The Alzheimer's Disease Assessment Scale-14 item Cognitive Subscale, hereafter referred to as ADAS-Cog (14), will be used for this assessment (see Attachment LZZT.2).
- To assess the treatment response as a function of Apo E genotype.

[illegible]

Raw Data

git Study Browser Home menu

SDTM LE Domain Data

Data generated from the database for the Laboratory Test Results domain

STUDY	DOMAIN	USUALDO	LESTED	LESTED1	LESTED2	LESTED3	LESTED4	LESTED5	LESTED6	LESTED7	LESTED8	LESTED9	LESTED10	LESTED11	LESTED12	LESTED13	LESTED14	LESTED15	LESTED16	LESTED17	LESTED18	LESTED19	LESTED20	LESTED21	LESTED22	LESTED23	LESTED24	LESTED25	LESTED26	LESTED27	LESTED28	LESTED29	LESTED30	LESTED31	LESTED32	LESTED33	LESTED34	LESTED35	LESTED36	LESTED37	LESTED38	LESTED39	LESTED40	LESTED41	LESTED42	LESTED43	LESTED44	LESTED45	LESTED46	LESTED47	LESTED48	LESTED49	LESTED50	LESTED51	LESTED52	LESTED53	LESTED54	LESTED55	LESTED56	LESTED57	LESTED58	LESTED59	LESTED60	LESTED61	LESTED62	LESTED63	LESTED64	LESTED65	LESTED66	LESTED67	LESTED68	LESTED69	LESTED70	LESTED71	LESTED72	LESTED73	LESTED74	LESTED75	LESTED76	LESTED77	LESTED78	LESTED79	LESTED80	LESTED81	LESTED82	LESTED83	LESTED84	LESTED85	LESTED86	LESTED87	LESTED88	LESTED89	LESTED90	LESTED91	LESTED92	LESTED93	LESTED94	LESTED95	LESTED96	LESTED97	LESTED98	LESTED99	LESTED100	LESTED101	LESTED102	LESTED103	LESTED104	LESTED105	LESTED106	LESTED107	LESTED108	LESTED109	LESTED110	LESTED111	LESTED112	LESTED113	LESTED114	LESTED115	LESTED116	LESTED117	LESTED118	LESTED119	LESTED120	LESTED121	LESTED122	LESTED123	LESTED124	LESTED125	LESTED126	LESTED127	LESTED128	LESTED129	LESTED130	LESTED131	LESTED132	LESTED133	LESTED134	LESTED135	LESTED136	LESTED137	LESTED138	LESTED139	LESTED140	LESTED141	LESTED142	LESTED143	LESTED144	LESTED145	LESTED146	LESTED147	LESTED148	LESTED149	LESTED150	LESTED151	LESTED152	LESTED153	LESTED154	LESTED155	LESTED156	LESTED157	LESTED158	LESTED159	LESTED160	LESTED161	LESTED162	LESTED163	LESTED164	LESTED165	LESTED166	LESTED167	LESTED168	LESTED169	LESTED170	LESTED171	LESTED172	LESTED173	LESTED174	LESTED175	LESTED176	LESTED177	LESTED178	LESTED179	LESTED180	LESTED181	LESTED182	LESTED183	LESTED184	LESTED185	LESTED186	LESTED187	LESTED188	LESTED189	LESTED190	LESTED191	LESTED192	LESTED193	LESTED194	LESTED195	LESTED196	LESTED197	LESTED198	LESTED199	LESTED200	LESTED201	LESTED202	LESTED203	LESTED204	LESTED205	LESTED206	LESTED207	LESTED208	LESTED209	LESTED210	LESTED211	LESTED212	LESTED213	LESTED214	LESTED215	LESTED216	LESTED217	LESTED218	LESTED219	LESTED220	LESTED221	LESTED222	LESTED223	LESTED224	LESTED225	LESTED226	LESTED227	LESTED228	LESTED229	LESTED230	LESTED231	LESTED232	LESTED233	LESTED234	LESTED235	LESTED236	LESTED237	LESTED238	LESTED239	LESTED240	LESTED241	LESTED242	LESTED243	LESTED244	LESTED245	LESTED246	LESTED247	LESTED248	LESTED249	LESTED250	LESTED251	LESTED252	LESTED253	LESTED254	LESTED255	LESTED256	LESTED257	LESTED258	LESTED259	LESTED260	LESTED261	LESTED262	LESTED263	LESTED264	LESTED265	LESTED266	LESTED267	LESTED268	LESTED269	LESTED270	LESTED271	LESTED272	LESTED273	LESTED274	LESTED275	LESTED276	LESTED277	LESTED278	LESTED279	LESTED280	LESTED281	LESTED282	LESTED283	LESTED284	LESTED285	LESTED286	LESTED287	LESTED288	LESTED289	LESTED290	LESTED291	LESTED292	LESTED293	LESTED294	LESTED295	LESTED296	LESTED297	LESTED298	LESTED299	LESTED300	LESTED301	LESTED302	LESTED303	LESTED304	LESTED305	LESTED306	LESTED307	LESTED308	LESTED309	LESTED310	LESTED311	LESTED312	LESTED313	LESTED314	LESTED315	LESTED316	LESTED317	LESTED318	LESTED319	LESTED320	LESTED321	LESTED322	LESTED323	LESTED324	LESTED325	LESTED326	LESTED327	LESTED328	LESTED329	LESTED330	LESTED331	LESTED332	LESTED333	LESTED334	LESTED335	LESTED336	LESTED337	LESTED338	LESTED339	LESTED340	LESTED341	LESTED342	LESTED343	LESTED344	LESTED345	LESTED346	LESTED347	LESTED348	LESTED349	LESTED350	LESTED351	LESTED352	LESTED353	LESTED354	LESTED355	LESTED356	LESTED357	LESTED358	LESTED359	LESTED360	LESTED361	LESTED362	LESTED363	LESTED364	LESTED365	LESTED366	LESTED367	LESTED368	LESTED369	LESTED370	LESTED371	LESTED372	LESTED373	LESTED374	LESTED375	LESTED376	LESTED377	LESTED378	LESTED379	LESTED380	LESTED381	LESTED382	LESTED383	LESTED384	LESTED385	LESTED386	LESTED387	LESTED388	LESTED389	LESTED390	LESTED391	LESTED392	LESTED393	LESTED394	LESTED395	LESTED396	LESTED397	LESTED398	LESTED399	LESTED400	LESTED401	LESTED402	LESTED403	LESTED404	LESTED405	LESTED406	LESTED407	LESTED408	LESTED409	LESTED410	LESTED411	LESTED412	LESTED413	LESTED414	LESTED415	LESTED416	LESTED417	LESTED418	LESTED419	LESTED420	LESTED421	LESTED422	LESTED423	LESTED424	LESTED425	LESTED426	LESTED427	LESTED428	LESTED429	LESTED430	LESTED431	LESTED432	LESTED433	LESTED434	LESTED435	LESTED436	LESTED437	LESTED438	LESTED439	LESTED440	LESTED441	LESTED442	LESTED443	LESTED444	LESTED445	LESTED446	LESTED447	LESTED448	LESTED449	LESTED450	LESTED451	LESTED452	LESTED453	LESTED454	LESTED455	LESTED456	LESTED457	LESTED458	LESTED459	LESTED460	LESTED461	LESTED462	LESTED463	LESTED464	LESTED465	LESTED466	LESTED467	LESTED468	LESTED469	LESTED470	LESTED471	LESTED472	LESTED473	LESTED474	LESTED475	LESTED476	LESTED477	LESTED478	LESTED479	LESTED480	LESTED481	LESTED482	LESTED483	LESTED484	LESTED485	LESTED486	LESTED487	LESTED488	LESTED489	LESTED490	LESTED491	LESTED492	LESTED493	LESTED494	LESTED495	LESTED496	LESTED497	LESTED498	LESTED499	LESTED500	LESTED501	LESTED502	LESTED503	LESTED504	LESTED505	LESTED506	LESTED507	LESTED508	LESTED509	LESTED510	LESTED511	LESTED512	LESTED513	LESTED514	LESTED515	LESTED516	LESTED517	LESTED518	LESTED519	LESTED520	LESTED521	LESTED522	LESTED523	LESTED524	LESTED525	LESTED526	LESTED527	LESTED528	LESTED529	LESTED530	LESTED531	LESTED532	LESTED533	LESTED534	LESTED535	LESTED536	LESTED537	LESTED538	LESTED539	LESTED540	LESTED541	LESTED542	LESTED543	LESTED544	LESTED545	LESTED546	LESTED547	LESTED548	LESTED549	LESTED550	LESTED551	LESTED552	LESTED553	LESTED554	LESTED555	LESTED556	LESTED557	LESTED558	LESTED559	LESTED560	LESTED561	LESTED562	LESTED563	LESTED564	LESTED565	LESTED566	LESTED567	LESTED568	LESTED569	LESTED570	LESTED571	LESTED572	LESTED573	LESTED574	LESTED575	LESTED576	LESTED577	LESTED578	LESTED579	LESTED580	LESTED581	LESTED582	LESTED583	LESTED584	LESTED585	LESTED586	LESTED587	LESTED588	LESTED589	LESTED590	LESTED591	LESTED592	LESTED593	LESTED594	LESTED595	LESTED596	LESTED597	LESTED598	LESTED599	LESTED600	LESTED601	LESTED602	LESTED603	LESTED604	LESTED605	LESTED606	LESTED607	LESTED608	LESTED609	LESTED610	LESTED611	LESTED612	LESTED613	LESTED614	LESTED615	LESTED616	LESTED617	LESTED618	LESTED619	LESTED620	LESTED621	LESTED622	LESTED623	LESTED624	LESTED625	LESTED626	LESTED627	LESTED628	LESTED629	LESTED630	LESTED631	LESTED632	LESTED633	LESTED634	LESTED635	LESTED636	LESTED637	LESTED638	LESTED639	LESTED640	LESTED641	LESTED642	LESTED643	LESTED644	LESTED645	LESTED646	LESTED647	LESTED648	LESTED649	LESTED650	LESTED651	LESTED652	LESTED653	LESTED654	LESTED655	LESTED656	LESTED657	LESTED658	LESTED659	LESTED660	LESTED661	LESTED662	LESTED663	LESTED664	LESTED665	LESTED666	LESTED667	LESTED668	LESTED669	LESTED670	LESTED671	LESTED672	LESTED673	LESTED674	LESTED675	LESTED676	LESTED677	LESTED678	LESTED679	LESTED680	LESTED681	LESTED682	LESTED683	LESTED684	LESTED685	LESTED686	LESTED687	LESTED688	LESTED689	LESTED690	LESTED691	LESTED692	LESTED693	LESTED694	LESTED695	LESTED696	LESTED697	LESTED698	LESTED699	LESTED700	LESTED701	LESTED702	LESTED703	LESTED704	LESTED705	LESTED706	LESTED707	LESTED708	LESTED709	LESTED710	LESTED711	LESTED712	LESTED713	LESTED714	LESTED715	LESTED716	LESTED717	LESTED718	LESTED719	LESTED720	LESTED721	LESTED722	LESTED723	LESTED724	LESTED725	LESTED726	LESTED727	LESTED728	LESTED729	LESTED730	LESTED731	LESTED732	LESTED733	LESTED734	LESTED735	LESTED736	LESTED737	LESTED738	LESTED739	LESTED740	LESTED741	LESTED742	LESTED743	LESTED744	LESTED745	LESTED746	LESTED747	LESTED748	LESTED749	LESTED750	LESTED751	LESTED752	LESTED753	LESTED754	LESTED755	LESTED756	LESTED757	LESTED758	LESTED759	LESTED760	LESTED761	LESTED762	LESTED763	LESTED764	LESTED765	LESTED766	LESTED767	LESTED768	LESTED769	LESTED770	LESTED771	LESTED772	LESTED773	LESTED774	LESTED775	LESTED776	LESTED777	LESTED778	LESTED779	LESTED780	LESTED781	LESTED782	LESTED783	LESTED784	LESTED785	LESTED786	LESTED787	LESTED788	LESTED789	LESTED790	LESTED791	LESTED792	LESTED793	LESTED794	LESTED795	LESTED796	LESTED797	LESTED798	LESTED799	LESTED800	LESTED801	LESTED802	LESTED803	LESTED804	LESTED805	LESTED806	LESTED807	LESTED808	LESTED809	LESTED810	LESTED811	LESTED812	LESTED813	LESTED814	LESTED815	LESTED816	LESTED817	LESTED818	LESTED819	LESTED820	LESTED821	LESTED822	LESTED823	LESTED824	LESTED825	LESTED826	LESTED827	LESTED828	LESTED829	LESTED830	LESTED831	LESTED832	LESTED833	LESTED834	LESTED835	LESTED836	LESTED837	LESTED838	LESTED839	LESTED840	LESTED841	LESTED842	LESTED843	LESTED844	LESTED845	LESTED846	LESTED847	LESTED848	LESTED849	LESTED850	LESTED851	LESTED852	LESTED853	LESTED854	LESTED855	LESTED856	LESTED857	LESTED858	LESTED859	LESTED860	LESTED861	LESTED862	LESTED863	LESTED864	LESTED865	LESTED866	LESTED867	LESTED868	LESTED869	LESTED870	LESTED871	LESTED872	LESTED873	LESTED874	LESTED875	LESTED876	LESTED877	LESTED878	LESTED879	LESTED880	LESTED881	LESTED882	LESTED883	LESTED884	LESTED885	LESTED886	LESTED887	LESTED888	LESTED889	LESTED890	LESTED891	LESTED892	LESTED893	LESTED894	LESTED895	LESTED896	LESTED897	LESTED898	LESTED899	LESTED900	LESTED901	LESTED902	LESTED903	LESTED904	LESTED905	LESTED906	LESTED907	LESTED908	LESTED909	LESTED910	LESTED911	LESTED912	LESTED913	LESTED914	LESTED915	LESTED916	LESTED917	LESTED918	LESTED919	LESTED920	LESTED921	LESTED922	LESTED923	LESTED924	LESTED925	LESTED926	LESTED927	LESTED928	LESTED929	LESTED930	LESTED931	LESTED932	LESTED933	LESTED934	LESTED935	LESTED936	LESTED937	LESTED938	LESTED939	LESTED940	LESTED941	LESTED942	LESTED943	LESTED944	LESTED945	LESTED946	LESTED947	LESTED948	LESTED949	LESTED950	LESTED951	LESTED952	LESTED953	LESTED954	LESTED955	LESTED956	LESTED957	LESTED958	LESTED959	LESTED960	LESTED961	LESTED962	LESTED963	LESTED964	LESTED965	LESTED966	LESTED967	LESTED968	LESTED969	LESTED970	LESTED971	LESTED972	LESTED973	LESTED974	LESTED975	LESTED976	LESTED977	LESTED978	LESTED979	LESTED980	LESTED981	LESTED982	LESTED983	LESTED984	LESTED985	LESTED986	LESTED987	LESTED988	LESTED989	LESTED990	LESTED991	LESTED992	LESTED993	LESTED994	LESTED995	LESTED996	LESTED997	LESTED998	LESTED999	LESTED1000	LESTED1001	LESTED1002	LESTED1003	LESTED1004	LESTED1005	LESTED1006	LESTED1007	LESTED1008	LESTED1009	LESTED1010	LESTED1011	LESTED1012	LESTED1013	LESTED1014	LESTED1015	LESTED1016	LESTED1017	LESTED1018	LESTED1019	LESTED1020	LESTED1021	LESTED1022	LESTED1023	LESTED1024	LESTED1025	LESTED1026	LESTED1027	LESTED1028	LESTED1029	LESTED1030	LESTED1031	LESTED1032	LESTED1033	LESTED1034	LESTED1035	LESTED1036	LESTED1037	LESTED1038	LESTED1039	LESTED1040	LESTED1041	LESTED1042	LESTED1043	LESTED1044	LESTED1045	LESTED1046	LESTED1047	LESTED1048	LESTED1049	LESTED1050	LESTED1051	LESTED1052	LESTED1053	LESTED1054	LESTED1055	LESTED1056	LESTED1057	LESTED1058	LESTED1059	LESTED1060	LESTED1061	LESTED1062	LESTED1063	LESTED1064	LESTED1065	LESTED1066	LESTED1067	LESTED1068	LESTED1069	LESTED1070	LESTED1071	LESTED1072	LESTED1073	LESTED1074	LESTED1075	LESTED1076	LESTED1077	LESTED1078	LESTED1079	LESTED1080	LESTED1081	LESTED1082	LESTED1083	LESTED1084	LESTED1085	LESTED1086	LESTED1087	LESTED1088	LESTED1089	LESTED1090	LESTED1091	LESTED1092	LESTED1093	LESTED1094	LESTED1095	LESTED1096	LESTED1097	LESTED1098	LESTED1099	LESTED1100	LESTED1101	LESTED1102	LESTED1103	LESTED1104	LESTED1105	LESTED1106	LESTED1107	LESTED1108	LESTED1109	LESTED1110	LESTED1111	LESTED1112	LESTED1113	LESTED1114	LESTED1115	LESTED1116	LESTED1117	LESTED1118	
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SDTM Data

[illegible]

Data Capture

How to build a model

Input data

- Age
- Gender
- Married
- Occupation

Model input

aC

Model output

- Income
- Married
- Occupation
- Age

aCRF

[illegible]

define.xml



Thank You



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cdisc