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A History of ISAR IPL Development

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IPL – Brief History

- Prior to 2012 various Registries had developed some sort of classification system for the implants they used
- These were sometimes fairly comprehensive and sometimes modest
- They were all somewhat different in scope and granularity
- Consequently comparison of results between registries was difficult leading to concerns –eg from Regulators such as FDA – that the systems could not allow pooling of data to recognize safety issues

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2011-2012

- Following discussions with FDA and others in 2011 several registries in ISAR agreed to work on a combined classification and library of hip and knee implants, funded by an FDA grant

- Plan was formulated to produce a spreadsheet with the combined data from Norway, Sweden, Australia and KP and with input later from various other registries

- This project was led from the start by S Graves with other ISAR Board members and coordinated within AOANJRR

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IPL – Brief History

- At ISAR Congress 2 in Stratford-on-Avon a meeting was held to gather support for both an International Prosthesis Library and harmonised global classification
- This would allow comparison and pooling of outcomes data confident that they were assessing the exact same implant variant
- All Registries could choose to adopt the system if they wished
- Alternatively the system could be used just as a library where they would seek details which they were missing
- Brand comparisons are simply too broad to be useful in this context

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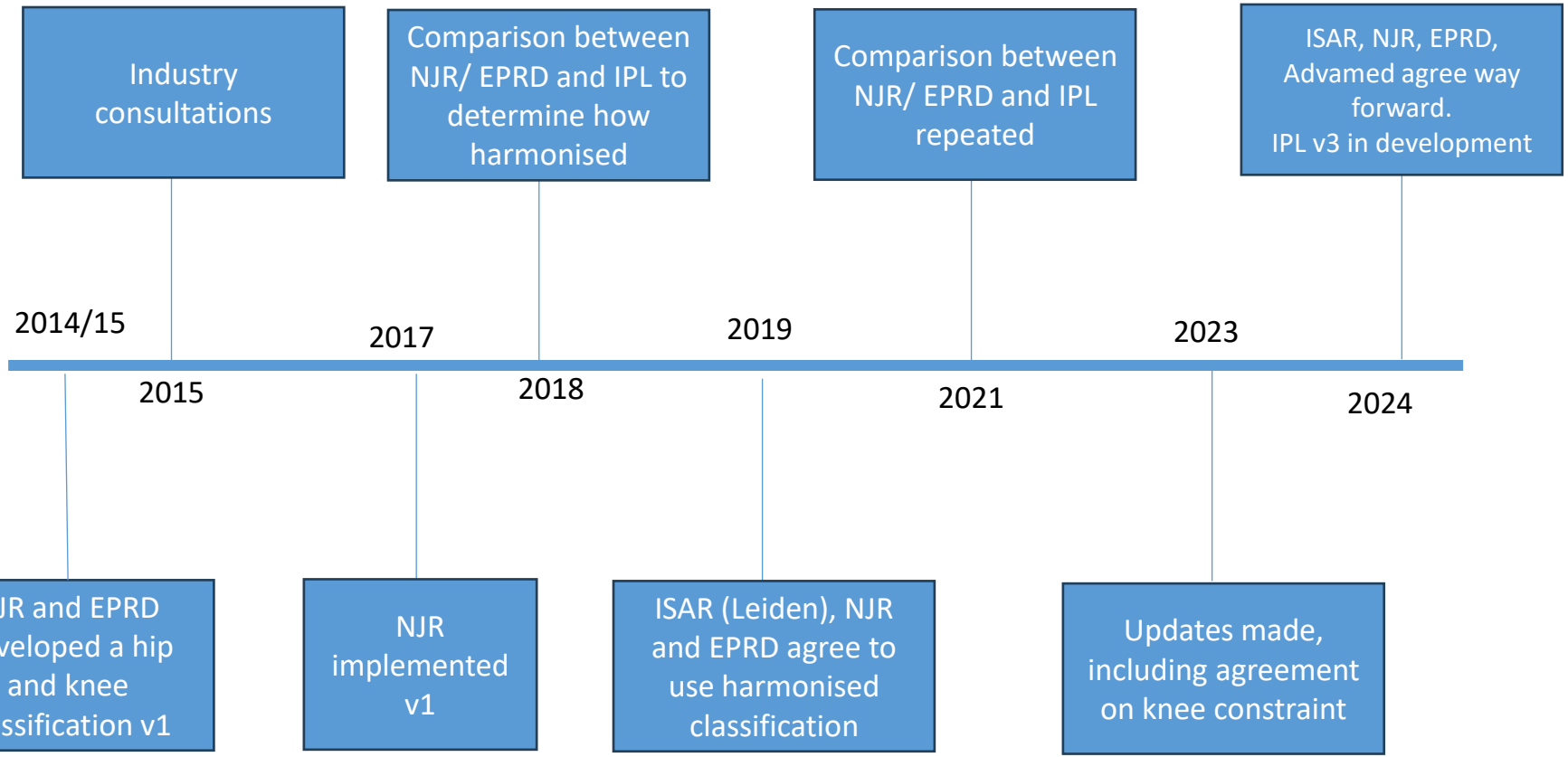
Brief History and timeline



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- Why is this all Necessary ?

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Detailed Nexgen Variant Analysis

CR Constructs Tibial - Bearing	All CR Nexgen Femoral Components	CR Option	CR Precoat	CR Porous	CR Flex Precoat	CR Flex GSF Precoat	CR Flex Porous
Stemmed Cemented Option - CR Flex Std	**82,684**	62,190	848	561	12,807	6,276	2
Stemmed Cemented Option - CR Flex Prolong	**1,605**	[illegible]	0	2	986	344	5
Stemmed Precoat - CR Flex Std	**8,203**	2,305	138	49	4,409	1,299	3
Stemmed Precoat - CR Flex Prolong	**2,090**	9	3	0	1,443	628	7
TM Tray - CR Flex Std	**219**	4	0	147	2	1	65
TM Tray - CR Flex Prolong	**91**	0	0	7	0	1	83
TM CR Monoblock	**4,264**	140	6	3,676	74	52	316
All Poly Tibia	**952**	803	1	0	39	109	0
All Tibial Components	**100,108**	**66,339**	**998**	**4,594**	**19,773**	**8,715**	**481**

PS Constructs Tibial - Bearing	All LPS Nexgen Femoral Components	LPS Option	LPS Porous	LPS Flex Option	LPS Flex GSF Option	LPS Flex Tivanium
Stemmed Cemented Option - LPS Flex Std	**69,372**	58,779	86	6,859	3,571	77
Stemmed Cemented Option - LPS Flex Prolong	**696**	76	0	345	74	201
Stemmed Precoat - LPS Flex Std	**9,184**	6,041	4	2,610	488	41
Stemmed Precoat - LPS Flex Prolong	**881**	8	0	248	168	457
LPS Fluted Precoat - LPS Std Mobile	**501**	0	0	345	156	0
TM Tray - LPS Flex Std	**370**	10	359	1	0	0
TM Tray - LPS Flex Prolong	**4**	0	3	0	0	1
TM LPS Monoblock	**1,888**	74	1,796	7	4	7
All Tibial Components	**82,896**	**70,704**	**2,263**	**11,458**	**4,652**	**785**

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Variant Analysis

- Huge numbers of variants within the Nexgen family
- All CR variant Tibias compatible with all CR variant Femoral implants (and similarly with PS to PS)
- Yet all can be seen to have very differing standardized Revision Ratios – some very high!

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IPL – Brief History

- Sadly there was disagreement about the degree of detail that was needed or desirable
- EPRD and NJR had already developed their systems to some extent and were keen for the data to be more granular and detailed (to detect such variants!)
- ISAR Board members dealing with this issue felt that a somewhat different and less granular system which they had already been working on was better
- Sadly, two systems therefore developed in parallel between 2013-2019
- NJR joined with the EPRD team and developed a single system together
- ISAR continued with their own system IPL v1

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IPL/NJR/EPRD Agreed Classification – Hip Example

Involves hundreds of attributes per item

Agreed definitions				
Joint type	**Class Component (sub g**	**Class Attribute**	**Class Value**	**Field Type**
Hip	**H1.1 Acetabular Component**	**Type ***	Modular	Single select
Hip	**H1.1 Acetabular Component**		Monobloc	
Hip	**H1.1 Acetabular Component**		Surface Replacement Cup	
Hip	**H1.1 Acetabular Component**		Preassembled	
Hip	**H1.1 Acetabular Component**		Prefixed	
Hip	**H1.1 Acetabular Component**		Reconstruction Shell	
Hip	**H1.1 Acetabular Component**		Dual Mobility	
Hip	**H1.1 Acetabular Component**	**3D Additive Printing Technology**	Yes	Single select
Hip	**H1.1 Acetabular Component**		No	
Hip	**H1.1 Acetabular Component**	**Revision Specific**	Yes	Single select
Hip	**H1.1 Acetabular Component**		No	
Hip	**H1.1 Acetabular Component**	**Patient Specific / Custom**	Yes	Single select
Hip	**H1.1 Acetabular Component**		No	
Hip	**H1.1 Acetabular Component**	**Articulation Diameter (*)**	22 mm	Single select
Hip	**H1.1 Acetabular Component**		22.25 mm	
Hip	**H1.1 Acetabular Component**		24 mm	
Hip	**H1.1 Acetabular Component**		26 mm	

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IPL – Brief History – Two systems

- This created a great problem because Manufacturers were being asked to complete the upload of attribute data about their implants for ISAR, NJR, EPRD and often for many other registries around the world
- Consequently they often did this reluctantly and some companies hardly at all!
- Most such databases over the next decade have therefore been incomplete and sometimes not fully fit for purpose
- One single database of implant characteristics therefore became the ‘sine qua non’ as far as Advamed manufacturers were concerned
- **ISAR agreed at a meeting Leiden (ISAR 2019) to adopt the more granular system developed by NJR/EPRD**

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IPLv1 Compared to NJR/EPRD in 2018 – Knee Results

Component Type	High Level Matching NJR/IPL Matched	Low Level Matching: NJR/IPL Matched	NJR Matched to IPL %	IPL Matched to NJR %
General (Component Identification)	100%	100%	100%	100%
K1.1 Femoral Component - All Types (Total / Uni / Bicompartmental / Pat Femoral)	79%	52%	92%	54%
K1.2 Tibial Tray, Including Monobloc - All Types (Total / Uni / Prefixed / Pre assembled)	80%	57%	93%	60%
K1.3 Tibial Insert - All Types (Total / Uni)	77%	68%	88%	75%
K1.4 Patella - All Types (Modular / Monobloc)	88%	36%	47%	60%
K1.5 Modular Stems	89%	44%	83%	49%
K1.6 Accessory Components	Not recorded on IPL			
K1.7 Femoral Augment	Not recorded on IPL			
K1.8 Tibial Augment	Not recorded on IPL			
K1.9 Complete Knee	Not recorded on IPL			
Total	**82%**	**53%**	**82%**	**60%**

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IPLv1 Compared to NJR/EPRD in 2018 – Hip Results

Component Type	High Level Matching	Low Level Matching: NJR/IPL Matched	NJR Matched to IPL %	IPL Matched to NJR %
General (Component Identification)	100%	100%	100%	100%
H1.1 Acetabular Component - All Types (Modular / Monobloc / Resurfacing / etc)	86%	59%	93%	62%
H1.2 Acetabular Insert - All Types	79%	69%	96%	72%
H1.3 Modular Head - All Types (Standard / BiPolar)	87%	77%	94%	81%
H1.4 Resurfacing Head	94%	69%	93%	73%
H1.5 Femoral Stem - All Types (Total / Uni / Monobloc / Modular / etc)	72%	44%	70%	54%
H1.6 Femoral Accessory Component - All Types (Distal stems / Modular Necks / etc)	42%	42%	83%	46%
H1.7 Acestabular Accessory Component - All Types (Acetabular Reinforcement Device / etc)	55%	23%	32%	43%
Total	**76%**	**57%**	**84%**	**64%**

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Progress between 2019 and 2022

- Despite the agreement between NJR, ISAR and EPRD in 2019 there continued to be problems

- 1 Manufacturers were still being asked to upload the data to several registries in different amounts and in different formats
- 2 The systems for those registries frequently were incompatible so transfer of the implant data was difficult or impossible
- 3 COVID happened almost immediately and stalled this amongst many things
- 4 The verbal agreement in Leiden had not been put into a clear and binding document between NJR/EPRD and ISAR

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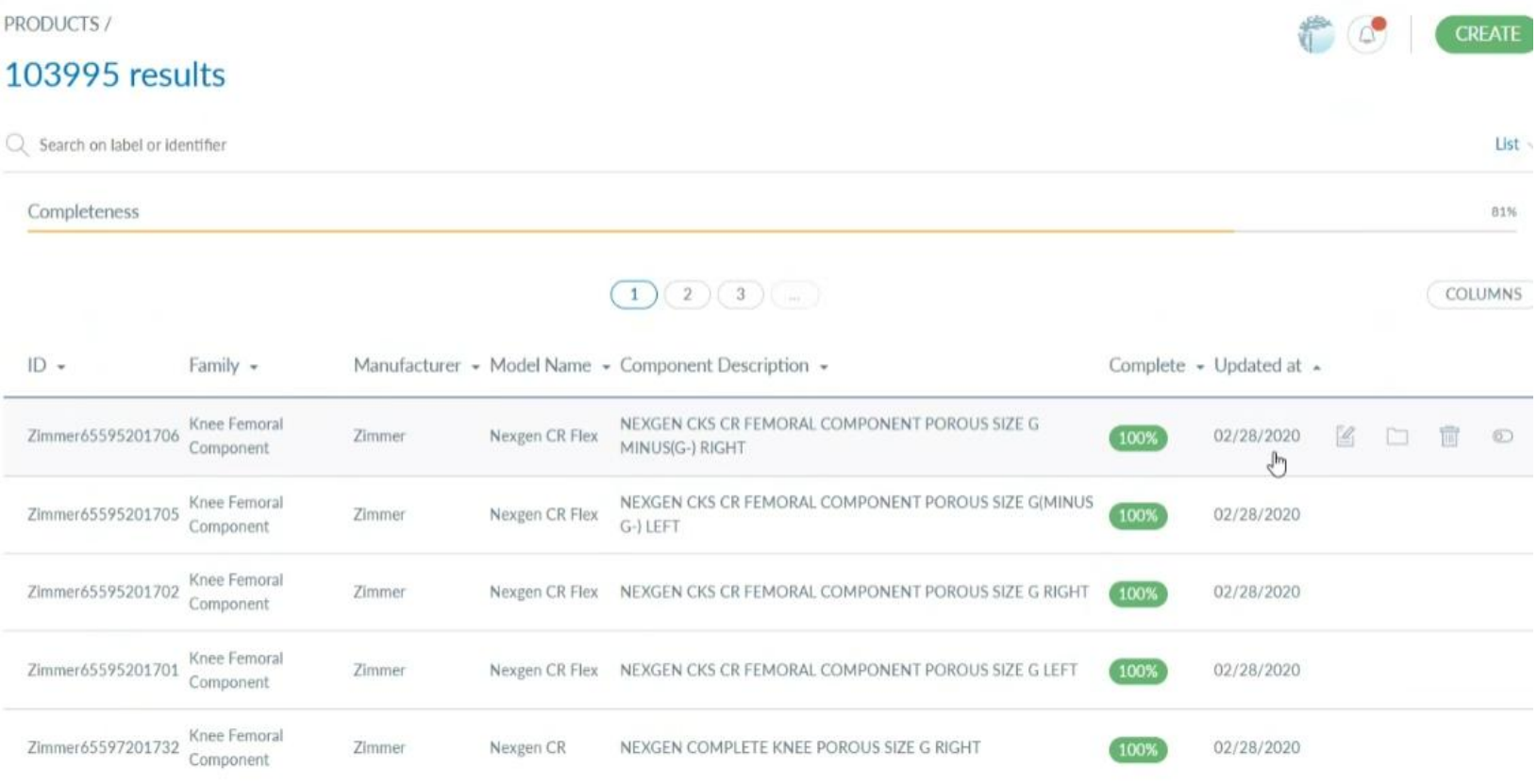
IPL Completeness varied considerably



ID	Family	Manufacturer	Model Name	Component Description	Complete	Updated at
Zimmer65595201706	Knee Femoral Component	Zimmer	Nexgen CR Flex	NEXGEN CKS CR FEMORAL COMPONENT POROUS SIZE G MINUS(G-) RIGHT	100%	02/28/2020
Zimmer65595201705	Knee Femoral Component	Zimmer	Nexgen CR Flex	NEXGEN CKS CR FEMORAL COMPONENT POROUS SIZE G(MINUS G-) LEFT	100%	02/28/2020
Zimmer65595201702	Knee Femoral Component	Zimmer	Nexgen CR Flex	NEXGEN CKS CR FEMORAL COMPONENT POROUS SIZE G RIGHT	100%	02/28/2020
Zimmer65595201701	Knee Femoral Component	Zimmer	Nexgen CR Flex	NEXGEN CKS CR FEMORAL COMPONENT POROUS SIZE G LEFT	100%	02/28/2020
Zimmer65597201732	Knee Femoral Component	Zimmer	Nexgen CR	NEXGEN COMPLETE KNEE POROUS SIZE G RIGHT	100%	02/28/2020

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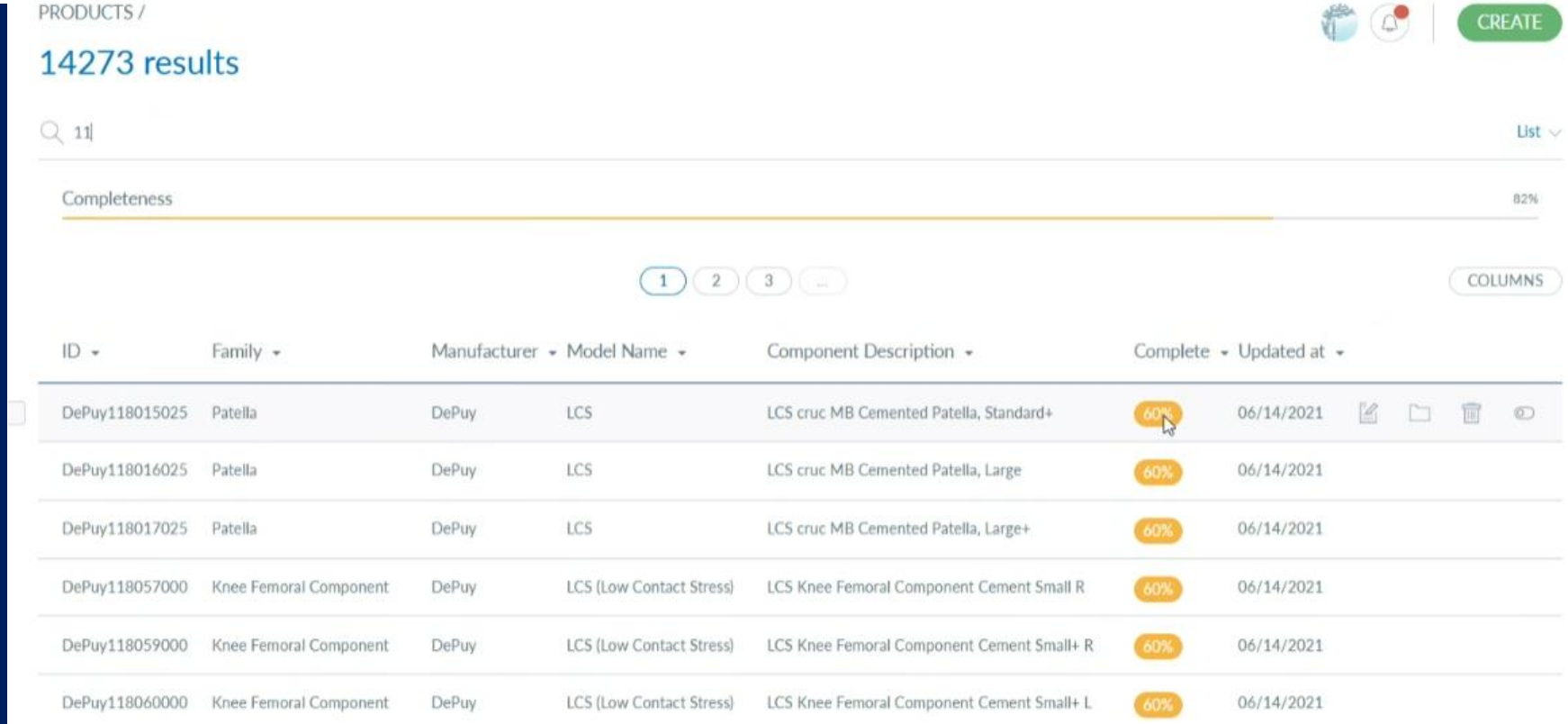
IPL completeness varied considerably



ID	Family	Manufacturer	Model Name	Component Description	Complete	Updated at
DePuy118015025	Patella	DePuy	LCS	LCS cruc MB Cemented Patella, Standard+	60%	06/14/2021
DePuy118016025	Patella	DePuy	LCS	LCS cruc MB Cemented Patella, Large	60%	06/14/2021
DePuy118017025	Patella	DePuy	LCS	LCS cruc MB Cemented Patella, Large+	60%	06/14/2021
DePuy118057000	Knee Femoral Component	DePuy	LCS (Low Contact Stress)	LCS Knee Femoral Component Cement Small R	60%	06/14/2021
DePuy118059000	Knee Femoral Component	DePuy	LCS (Low Contact Stress)	LCS Knee Femoral Component Cement Small+ R	60%	06/14/2021
DePuy118060000	Knee Femoral Component	DePuy	LCS (Low Contact Stress)	LCS Knee Femoral Component Cement Small+ L	60%	06/14/2021

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Since 2022

- The ISAR Board renewed attempts to get a binding and workable agreement and regular meetings with Advamed and interested parties were held
- P Voorhurst and Rob Neher have been great champions of this process and have worked hard with us to achieve an agreement
- Problems persisted that Advamed had agreements with AAOS/AJRR and wanted to upload their attribute data into that system and not elsewhere in the world – above all only ONCE
- This proved to be more difficult than thought so agreement was reached to upload the data to NJR, and to AJRR as soon as they were ready

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Current agreement

- NEC on behalf of NJR has matched the databases and identified the missing data in both
- Imminently manufacturers will be sent their own data in a spreadsheet with all implant attribute data already in either AJRR or NJR already completed
- Manufacturers will be asked to complete the missing data and return it
  - To NJR if their implants are already used there
  - To IPL if they are NOT used in UK and if AJRR is ready to receive them in the new format
  - To NJR if AJRR is not yet ready and NJR will upload the data to IPL Later
  - Once completed, NJR and IPL will share each others implant attribute data

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How can the harmonised global classification be used?

- Registry data sharing – with enhanced confidence
- Grouping products into constructs for reporting based on attributes (reporting analysis unit)
- Implant reporting – reporting on constructs and splitting out variations within product families
- Outlier detection
- Possibly for Global Benchmarking
- Possibly for more sophisticated early warning systems about implant variants

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Modular Neck Hip Stems

Bespoke Report on: Modular neck stems

Brand usage by year

Stem Manufacturer	Stem Brand	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	Total
																						17	39	11	67
					2	13	17	13	8	5	2														60
									34	34															68
									100	133	48	8	10												299
		63	69	90	73	105	113	110	104	106	80	61	16												990
									4	2	5	19	8	1					9	6	10	7	8		79
			11	96	195	177	276	373	574	587	550	397	338	199	126	98	59	76	38	23	24	23	20		4260
											46	48	4	3											101
							46	171	142	176	188	60	57	47	46	29	32	24	3	9	6	4			1040
					22	9	25	20	30	45	58	63	66	72	65	72	71	102	24	24	66	81	43		958
				4	7	8	64	65	57	62	67	10	10	6	16	4	11	15	8	36	45	20			515
										5	6														11
								14	19	12	1														46
									14	7	4	10	25	3											63
						14	55	97	96	131	184	108	56	37	44	19	3								844
					1	3	29	67	182	284	292	141	61	10	5	1	1	1							1078
Total		63	80	190	300	329	625	930	1364	1589	1531	925	651	378	302	223	177	218	82	98	151	152	110	11	10479

Year Implanted	Titanium SHORT	Titanium LONG	Cobalt Chrome SHORT	Cobalt Chrome LONG
2003	-	1	-	-
2004	10	2	-	-
2005	75	24	-	-
2006	138	90	-	-
2007	134	59	-	-
2008	291	121	-	-
2009	425	203	-	-
2010	562	244	-	1
2011	603	252	-	17
2012	591	75	8	240
2013	358	9	28	202
2014	286	18	10	169
2015	166	14	11	137
2016	164	5	-	84
2017	136	1	-	66
2018	139	-	-	34
Total	4078	1118	57	950

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Bespoke Report on:

Modular neck stems

Combinations Implanted - excluding MoM

Stem Manufacturer	Stem Brand	Stem Material	Neck Material / Type: Titanium SHORT	Titanium LONG	All Titanium	Cobalt-Chrome SHORT	Cobalt-Chrome LONG	All Cobalt-Chrome
		Titanium	45	5	50	-	29	29
		Titanium	2,321	784	3,110	24	840	864
		Titanium	11	2	13	32	56	88
		Titanium	775	128	905	1	64	65
		Titanium	418	16	434	-	15	15
		Cobalt-Chrome	752	75	827	-	129	129
		Unknown	-	-	2	-	-	-
		Titanium	-	-	67	-	-	-
		Titanium	-	-	1	-	-	30
		Titanium	-	-	160	-	-	139
		Titanium	-	-	938	-	-	31
		Titanium	-	-	14	-	-	49
		Titanium	-	-	221	-	-	597
		Titanium	-	-	1,062	-	-	-
		Unknown	-	-	-	-	-	43
		Titanium	-	-	-	-	-	11

Bespoke Report on:

Modular neck stems

Revision Rate Ratio (Excluding MoM)

Stem Manufacturer	Stem Brand	Stem Material	Neck Material / Type: Titanium SHORT	Titanium LONG	All Titanium	Cobalt-Chrome SHORT	Cobalt-Chrome LONG	All Cobalt-Chrome
		Titanium	0.00 (0.19 - 1.39)	0.00 (0.24 - 1.75)	0.00 (0.18 - 1.30)	-	0.00 (0.21 - 1.56)	0.00 (0.21 - 1.55)
		Titanium	1.18 (1.03 - 1.32)	1.40 (1.13 - 1.63)	1.24 (1.11 - 1.36)	0.00 (0.20 - 1.42)	2.31 (1.85 - 2.59)	2.24 (1.80 - 2.52)
		Titanium	2.57 (0.46 - 2.22)	-	2.13 (0.44 - 2.16)	0.81 (0.34 - 1.64)	0.97 (0.43 - 1.64)	0.91 (0.46 - 1.50)
		Titanium	0.91 (0.69 - 1.15)	2.11 (1.20 - 2.47)	1.10 (0.87 - 1.33)	-	2.32 (0.85 - 2.48)	2.28 (0.84 - 2.47)
		Titanium	0.80 (0.54 - 1.14)	0.00 (0.21 - 1.53)	0.77 (0.52 - 1.10)	-	0.00 (0.22 - 1.63)	0.00 (0.22 - 1.62)
		Cobalt-Chrome	0.56 (0.39 - 0.86)	1.06 (0.50 - 1.66)	0.64 (0.46 - 0.92)	-	0.83 (0.40 - 1.51)	0.83 (0.39 - 1.52)
		Unknown	-	-	0.96 (0.77 - 1.17)	-	-	-
		Titanium	-	-	0.00 (0.22 - 1.60)	-	-	-
		Titanium	-	-	-	-	-	1.98 (0.69 - 2.27)
		Titanium	-	-	1.27 (0.72 - 1.73)	-	-	2.48 (1.34 - 2.76)
		Titanium	-	-	1.68 (1.41 - 1.90)	-	-	7.32 (1.65 - 4.17)
		Titanium	-	-	2.25 (0.45 - 2.18)	-	-	6.04 (2.01 - 4.41)
		Titanium	-	-	1.41 (0.95 - 1.78)	-	-	1.61 (1.24 - 1.90)
		Titanium	-	-	0.96 (0.77 - 1.17)	-	-	-
		Unknown	-	-	-	-	-	5.22 (1.76 - 4.02)
		Titanium	-	-	-	-	-	0.00 (0.21 - 1.54)

Revised / Expected (80% Credible Interval)
Adjusted for patient age and gender

LCI > 2x expected	UCI < 1/2 expected
LCI > 1.5x expected	UCI < 2/3 expected
LCI > 1.2x expected	UCI < 5/6 expected

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Unique Device Identifier (UDI)

- Is this not all provided by the UDI?
- UDI is a signpost to the attribute data
- UDI may in some cases contain SOME indications of attributes but
- Does NOT contain the detail and granularity and inmost cases not the attribte data itself

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Thank you

Contact Details

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