



Results to 31 Dec 2021

June 2022

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High performing results – Designed to reflect the clinical reality

Independent validation

The test withstood the rigours of being developed and trained in one cohort while being independently validated in another cohort.

International, multi-center, prospective study.

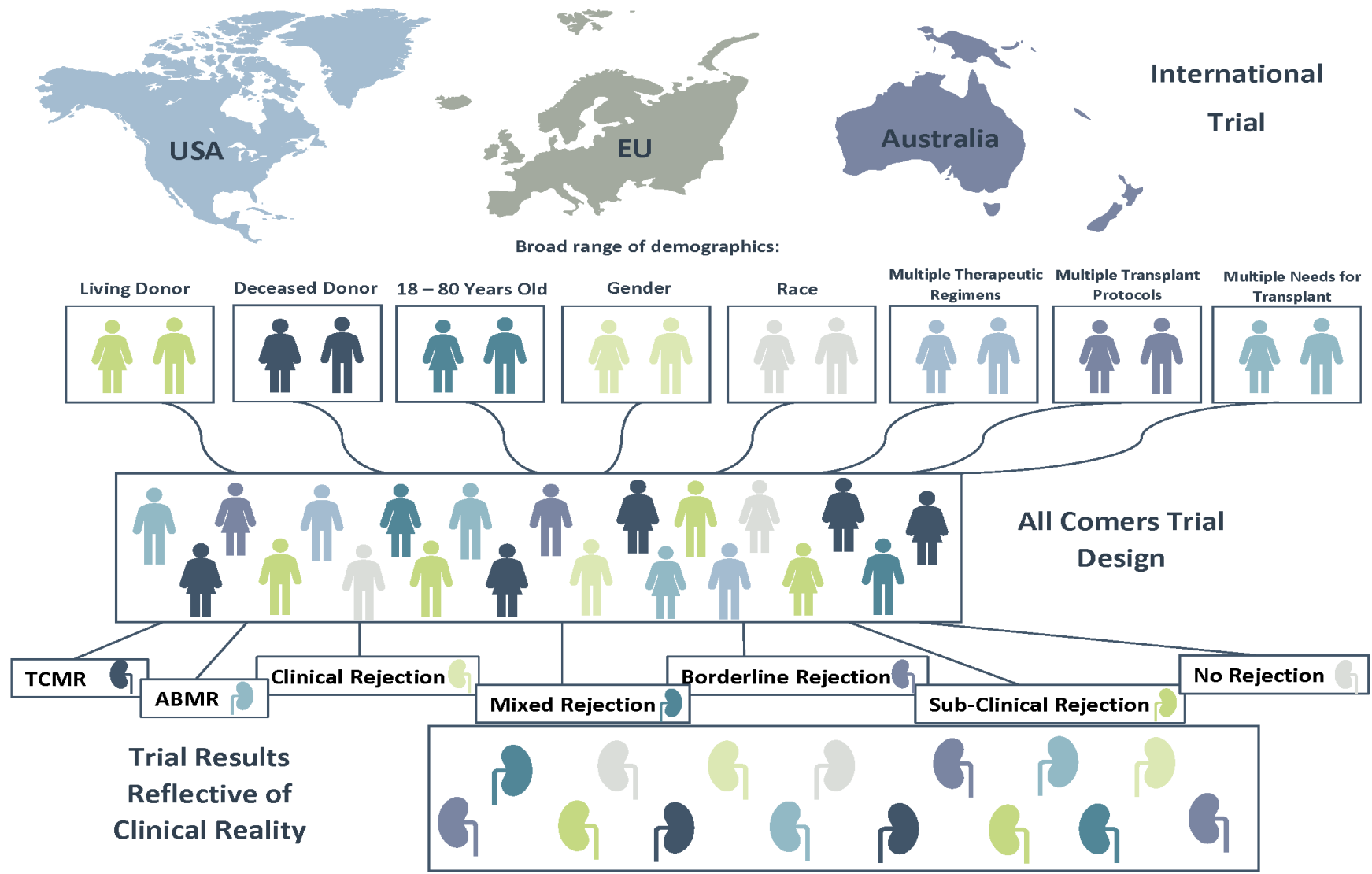
Fully validated

Our study includes all timepoints in the first six months post-transplant and included both surveillance and for-cause biopsies. This is an all-comers approach, the highest way to stress-test a diagnostic.

Tuteva picks up both subclinical and clinical rejection caused by both T-Cell and B-Cell (antibody) mediated means and of **all** levels of severity, including *borderline*.

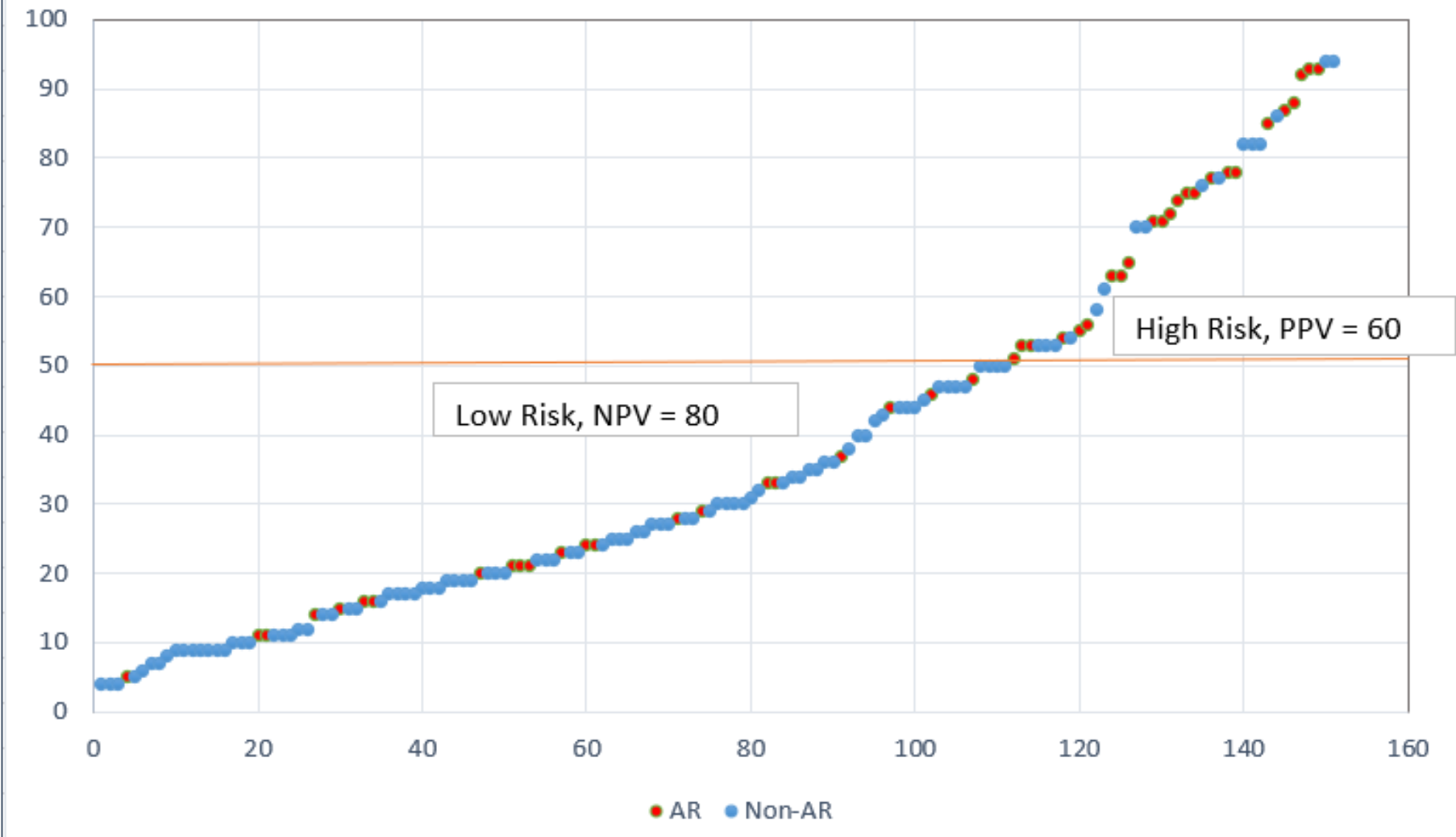
Performed in a COVID environment

Now part of the clinical reality but not well understood at the outset

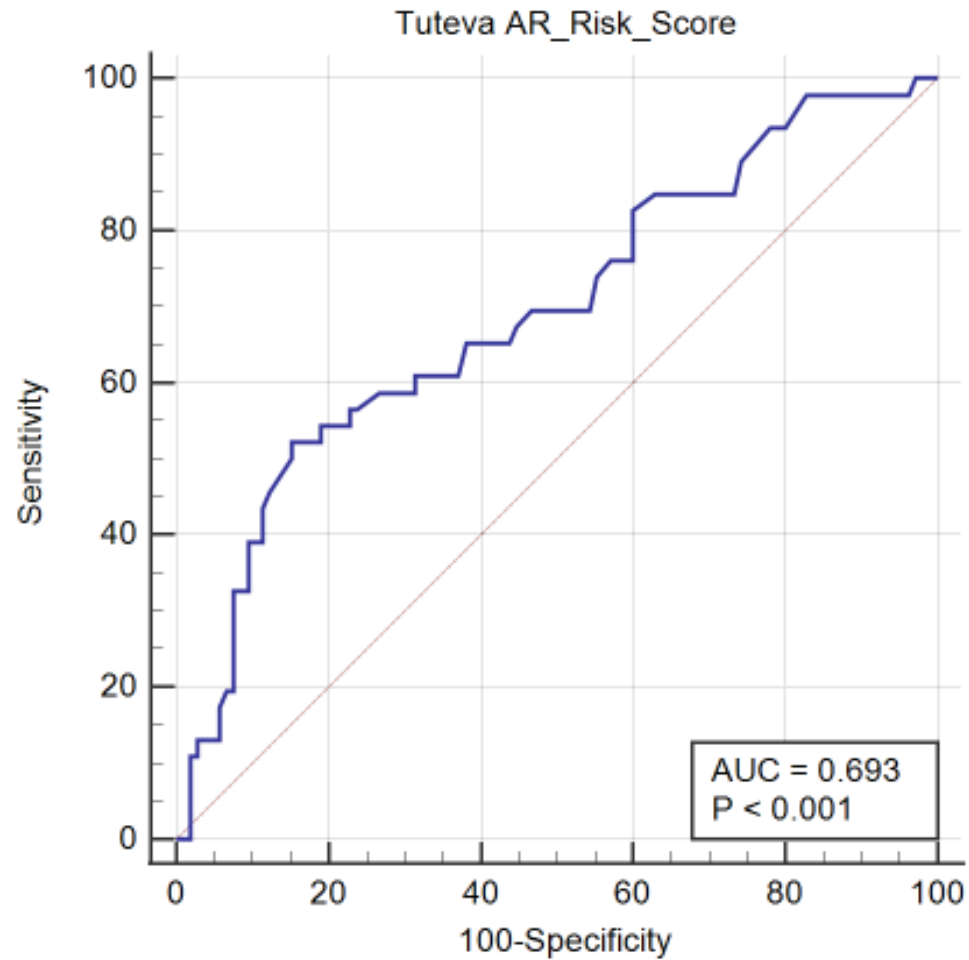


Tuteva™ Clinical Validation Study Demographics			
151 Unique Study Participants		Living Donor Recipient	51 Total
Mean/Median Recipient Age	53/53 Years	Living Related Donor	28
Mean/Median Donor Age	47/46 Years	Living Unrelated Donor	23
Male	97 (64%)	Deceased Donor Recipient	100 Total
Female	54 (36%)	Standard Criteria Donor	51
Donor Specific Antibodies		Expanded Criteria Donor	17
Anti HLA AB Class I	11%	Donors after Cardiac Death	31
Anti HLA AB Class II	12%	Not Answered (Deceased)	1
Race		Underlying Causality	Percentage of Cohort
Asian	5	Diabetes	21%
Black	31	Hypertension	74%
Native American	0	Glomerulonephritis	19%
Pacific Islander	3	Polycystic Kidney Disease	12%
White	108	Congenital Abnormality	3%
Not Answered	4	Family History of Kidney Disease	4%
Pathology Phenotype		Participation Location	
Rejection	46 (30%)	USA	84
No Rejection	105 (70%)	Europe/Australia	57/10

Tuteva AR Event Chart



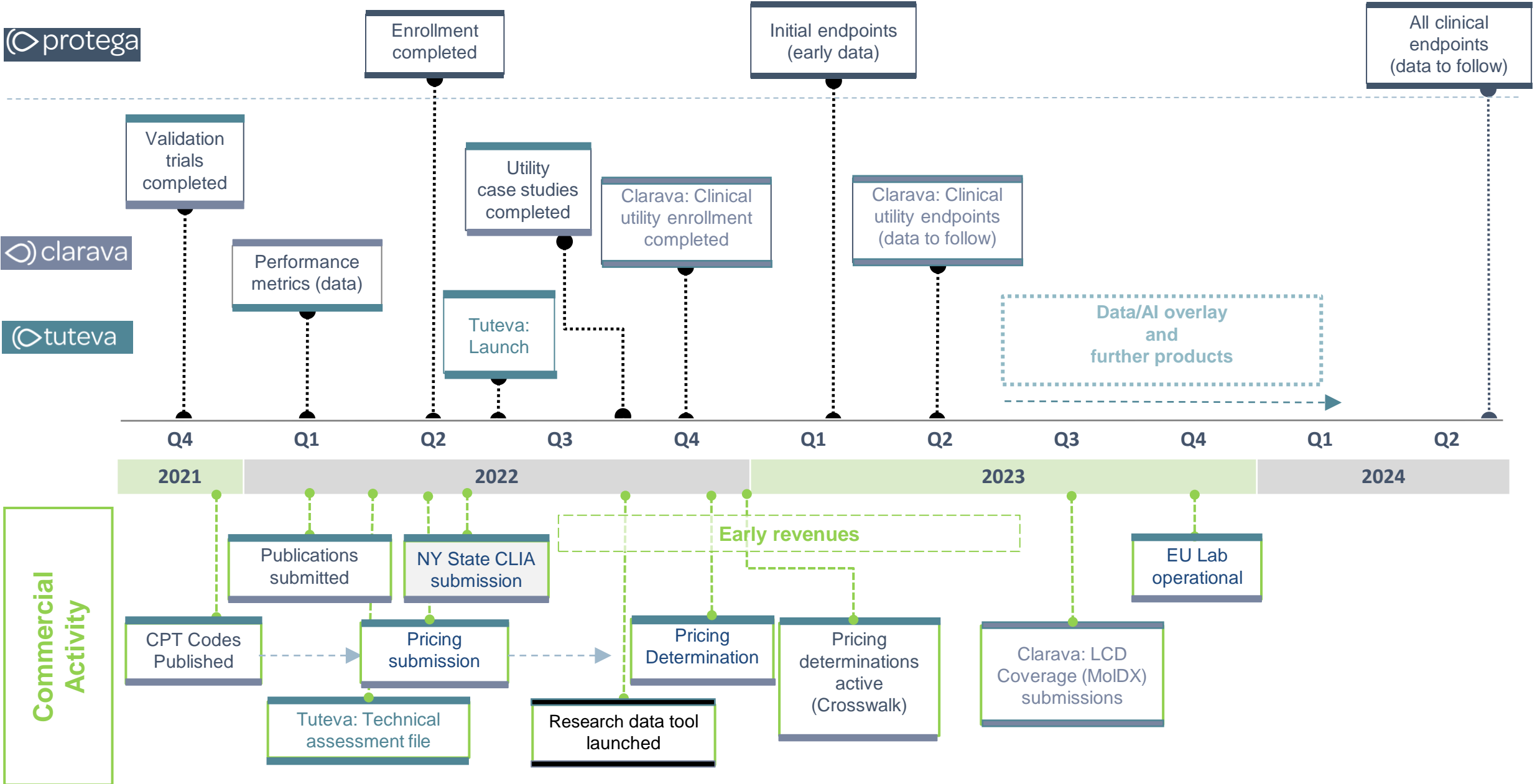
- All evaluable participants (n = 151, table 1) enrolled at 13 centers in 5 countries were included in the Tuteva validation. Each study participant had blood collected at the time of for-cause (n = 44) or protocol biopsy (n = 107) within the first 6 months following transplant.
- Each biopsy was read centrally by an expert in renal pathology to identify and characterize rejection phenotypes. In 151 unique patients, 46 (30%) rejection events were characterized (table 2) according to current (2019) BANFF criteria, including borderline TCMR³. Mean time to rejection was 61.1 days; range: 6 - 175d. Additionally, BK Nephropathy was identified in 8 patients and pyelonephritis in 3 patients.
- Tuteva risk scores are calculated continuously from 0-100; for interpretation, a pre-determined risk cut-point of 50 was established based on the independent training set¹. The risk score distribution (fig. 2) resulted in 26.5% of patients with a high risk (>50) score result in which 60% were shown to correlate with rejection on histopathology; low risk score results in 73.5% of patients correlated with an absence of rejection on histopathology findings in 80% of patients. The receiver operating characteristic curve AUC was 0.693, P<0.001 (fig. 3).
- A subset of 12 participants had multiple biopsies for which differentiated results of rejection and non-rejection were found and for which there was a correlated blood sample from which Tuteva results were calculated, allowing a limited assessment of Tuteva signature response to changing pathology phenotypes, table 3.



BANFF 2019 ²	# Detected/ # Cases
Borderline	5/12
TCMR IA or higher	3/13
ABMR	7/11
Mixed	9/10
BKN Negative	7/8
Pyelonephritis Negative	1/3

Patient	Tuteva Risk Score	Risk Score Interpretation	Days between Biopsies	Biopsy	Biopsy Histopathology Phenotype
1	93	High	71	For-cause	Rejection
	7	Low		Protocol	No Rejection
2	99	High	73	For-cause	Rejection
	75	High		Protocol	No Rejection
3	71	High	73	For-cause	Rejection
	25	Low		Protocol	No Rejection
4	72	High	21	For-cause	Rejection
	48	Low		For-cause	No Rejection
5	71	High	64	For-cause	Rejection
	7	Low		Protocol	No Rejection
6	23	Low	34	Protocol	No Rejection
	5	Low		For-cause	Rejection
7	77	High	87	For-cause	Rejection
	48	Low		Protocol	No Rejection
8	74	High	92	For-cause	Rejection
	90	High		Protocol	No Rejection
9	54	High	75	For-cause	Rejection
	30	Low		Protocol	No Rejection
10	50	Low	29	For-cause	No Rejection
	37	Low		For-cause	Rejection
11	63	High	95	For-cause	Rejection
	38	Low		Protocol	No Rejection
12	93	High	117	For-cause	Rejection
	60	High		Protocol	No Rejection

Indicative Robust Clinical Pathway to Revenues



Progress

Tuteva

- Presented initial data to clinical community at American Transplant Congress (ATC) June 4-8, 2022
 - Was selected to be highlighted at the What's Hot: What's New session
- Submitted to CMC pricing committee in June
- Hired commercial team and on track for soft launch prior to end of 2022
- Preparing file to Palmetto under local coverage determination (LCD) criteria

Clarava

- Still collecting HLA data and final biopsies
- Presented to CMC pricing committee in June
- Set up utility studies – 3 centers identified

Financial Results for the Year ended 31 December 2021

- Cash as at 31 December 2021 - \$10.3m
- March 2022 share issue raised gross proceeds of GBP10.0m c. \$13.0m
- Combined funds to be used:
 - To maintain momentum on development of Protega;
 - To build the expanded CLIA laboratory in Tennessee;
 - To commercialise Clarava and Tuteva;
 - To explore growth opportunities;
 - To develop nascent data assets; and
 - To continue to fund working capital

Cash Flow Statement

Year to 31 December 2021

	\$'000
Net outflow from operating activities	(6,336)
Investing activities	(966)
Financing activities	(73)
Net reduction in cash	(7,375)
Cash at 31 December 2021	10,340

Comments

- Operating flows – large increase in accruals for costs from trial sites reducing cash impact of EBITDA loss
- Investing flows – capital spend on equipment (\$618k) and spend on licenses / patents (\$348k)
- Financing flows – loan repayment settled in March 2021

Income Statement

Year to 31 December 2021

	\$'000
Administrative expenses	(7,151)
Depreciation and amortisation	(438)
Share based payments charge	(741)
Loss for the year	(8,330)

Comments

- Adjusted (for share based payments) EBITDA loss \$7.1m
- Largest items of expenditure:
 - Wages - \$1.9m
 - R&D - \$2.8m

Balance Sheet

As of 31 December 2021

	\$'000
Tangible assets	786
Intangible assets	2,008
Receivables	656
Cash at bank	10,330
Trade and other payables	(1,804)
Share capital	(182)
Share premium / share-based payments / foreign exchange reserves	(24,859)
Accumulated losses	13,065

Comments

- Intangible – cost of original license from Renalytix \$1.5m and additional spend on licences and patents
- Receivables – mainly prepayments \$406k
- Payables – mainly accruals \$1.6m, of which main component is costs from trial sites not yet billed

Vision: An integrated platform yielding rich data asset for innovation

