RAPID MEDICAL™ | DISTALS

International Stroke Conference

PRIMARY RESULTS OF THE DISTALS RANDOMIZED TRIAL OF TIGERTRIEVER 13 - EVT FOR DMVO

Saver JL[1] (co-first author), **Gupta R[2] (co-first author)**, Guenego A[3], Hassan AE[4], Jadhav AP[5], Siddiqui A[6], Taqi A[7], Zaidat O[8], Liebeskind DM[9], Fiorella D[10] (co-senior author), Chapot R (co-senior author)[11], for the DISTALS Investigators

[1] UCLA Comprehensive Stroke, Geffen School of Medicine, Los Angeles, CA, USA
[2] Department of Neurosurgery, WellStar Health System, Marietta, Georgia, USA.
[3] Interventional Neuroradiology Department Hôpital Universitaire de Bruxelles (HUB), Brussels, Belgium
[4] Department of Neurology (A.E.H.), University of Texas Rio Grande Valley-Valley Baptist Medical Center, Harlingen, Texas, USA
[5] Department of Neurosurgery, Barrow Neurological Institute, Phoenix, AR (A.P.J.), USA
[6] Department of Neurosurgery, Jacobs School of Medicine and Biomedical Sciences, University at Buffalo, Buffalo , New York , USA.
[7] Los Robles Hospital and Medical Center, Thousand Oaks, CA, USA
[8] Department of Neurology, Mercy Health - St Vincent Medical Center, Toledo, OH, USA.
[9] The University of Southern California Neurovascular Center, USC, Los Angeles CA, USA
[10] Department of Neurosurgery, Stony Brook University, Stony Brook, New York, USA.
[11] Alfried-Krupp-Hospital, Essen, Germany.

American Stroke Association. A division of the American Heart Association.

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DISCLOSURES

Dr. Rishi Gupta

Consultant

- Rapid Medical

Steering committee

- MEMBRANE Trial, Cerenovus
- Medtronic ELEVATE trial

LEADERSHIP AND COMMITTEES

National Principal Investigators	• Jeffrey L. Saver MD, UCLA, Los Angeles, CA • Rishi Gupta MD, WellStar, Marietta, GA • David Fiorella MD PhD, Stony Brook, Stony Brook, NY • René Chapot MD, Alfried-Krupp Krankenhaus, Essen, GERMANY
Trial Steering Committee	• Adnan Siddiqui MD, UBNS, Buffalo, NY • Sam Zaidat MD, Mercy, Toldeo, OH • Ameer Hassan MD, Valley Baptist, Harlingen, TX • Ashutosh Jadhav MD, Barrow, Phoenix, AZ • Asif Taqi MD, Los Robles, Thousand Oaks, CA • Adrien Guenego MD, Hopital Erasme, Brussels, BELGIUM
DSMB- Data Safety Monitoring Board	• Josh Hirsch MD, Mass General Hospital, Boston, MA (Chair) • Thabele (Bay) Leslie-Mazwi MD, University of Washington, Seattle, WA • Robert W. Regenhardt, M.D., Ph.D, Mass General Hospital, Boston, MA • Scott Hamilton, PhD Stanford Stroke Center, Stanford, CA
CEC- Clinical Events Committee	• Shazam Hussain MD, Cleveland Clinic, Cleveland, OH (Chair) • Shaye Moskowitz MD, Broward Health, Florida • Phillip Meyers MD, St. Luke's, Boise, ID
Brainstorme Neurovascular Imaging Core Lab	• David Liebeskind MD MBA, USC, Los Angeles, CA
CRO	• IQVIA
Statistical analysis	• Biomedical Statistical Consulting LLC

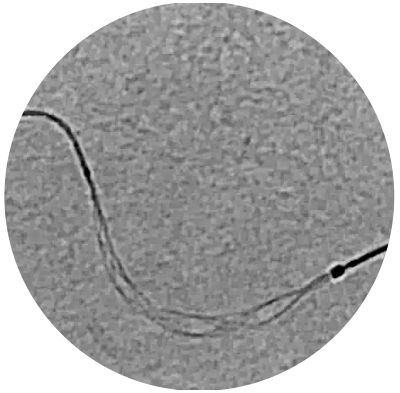
THE UNMET NEED

DMVO Stroke Treatment

- **Current Rx approach of medical therapy alone (IV lysis and/or antiplatelets) is insufficient**
  - ↪ High rates of global disability outcome with current treatment approaches
- **DMVO strokes are common but under-targeted and understudied**
  - ↪ Distal Medium Vessel Occlusions (DMVO) represent over 25% of ischemic strokes, yet have historically lacked dedicated devices or clinical trials
- **First three randomized EVT trials failed to deliver**
  - ↪ DMVO trials showed no clinical benefit, likely in part due to use of non-specialized endovascular devices

TIGERTRIEVER 13

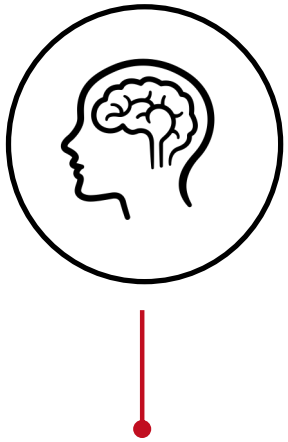
- **Investigational for DMVO in the USA under DISTALS IDE study**



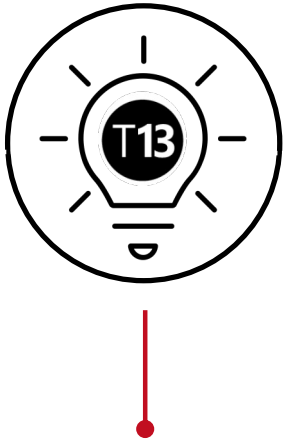
- Low delivery profile, 1.3 Fr microcatheter compatible
- Complete visibility and adjustability
- Adjust in small increments to tailor to the anatomy

DISTALS – DESIGNED FOR DMVO TREATMENT

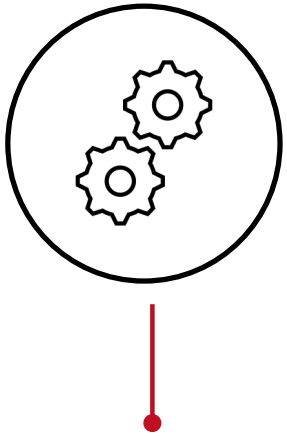
- **FDA-approved** DMVO IDE study
- Independent Imaging Core Lab



- **Penumbra imaging-based** selection
- Mismatch ratio of at least 2.0



- TIGERTRIEVER™ 13 is the only adjustable clot retriever **specifically designed** for the treatment of distal medium vessels occlusions.
- **Controllable & Flexible**



- **Mechanical thrombectomy** is the only treatment modality under test. Patients receiving tPA are excluded.

OBJECTIVE AND DESIGN

Distal Ischemic Stroke Treatment with Adjustable Low-profile Stentriever → DISTALS

- To evaluate the safety and effectiveness of the Tigertriever 13 Revascularization Device in restoring blood flow in the neurovasculature in patients presenting within 24 hours of onset with an ischemic stroke with disabling neurological deficits due to a primary distal vessel occlusion (DMVO).
- US and EU, multi-center, prospective, randomized, blinded (endpoint), controlled, IDE study
  - Randomization 1:1
    - Treatment: Medical Management + Tigertriever 13
    - Control: Medical Management
- Sample size - 168 patients (118 randomized + up to 50 lead-in) in up to 25 total centers
- Interim safety analysis after the enrollment and discharge of the first 50 US Tigertriever 13-treated subjects

TRIAL ENDPOINTS

ENDPOINT	MEASURE
Primary Effectiveness and Safety Composite	**Successful reperfusion* (CTP or MR PWI) without sICH**** *Successful reperfusion defined as >50% reduction in substantial hypoperfusion (Tmax >4 seconds) volume between baseline and 24 ±6 hours of randomization. **sICH defined as local or remote PH2 as detected on 24±6 hours post-procedure CT combined with a neurologic deterioration of ≥4 points NIHSS deterioration at 24 hours (±6 hours) of randomization or hemorrhage leading to death within 24 hours (SITS-MOST).
Secondary Effectiveness	• Successful reperfusion (eTICI ≥2b50) (treatment arm only) • Disability level @ 90 days (mRS shift-tetrachotomized: 0, 1, 2, 3-6) • NIHSS change from baseline to day 4/discharge • Health-related quality of life (EQ-5D) at 90 days • Cognitive function at 90 days (Montreal Cognitive Assessment, MoCA)
Secondary Safety	• All cause mortality @ 90 days • Any asymptomatic intracranial hemorrhage within 24 hours • Device/procedure related serious adverse events (SAEs) • Unanticipated adverse device effect (UADEs)

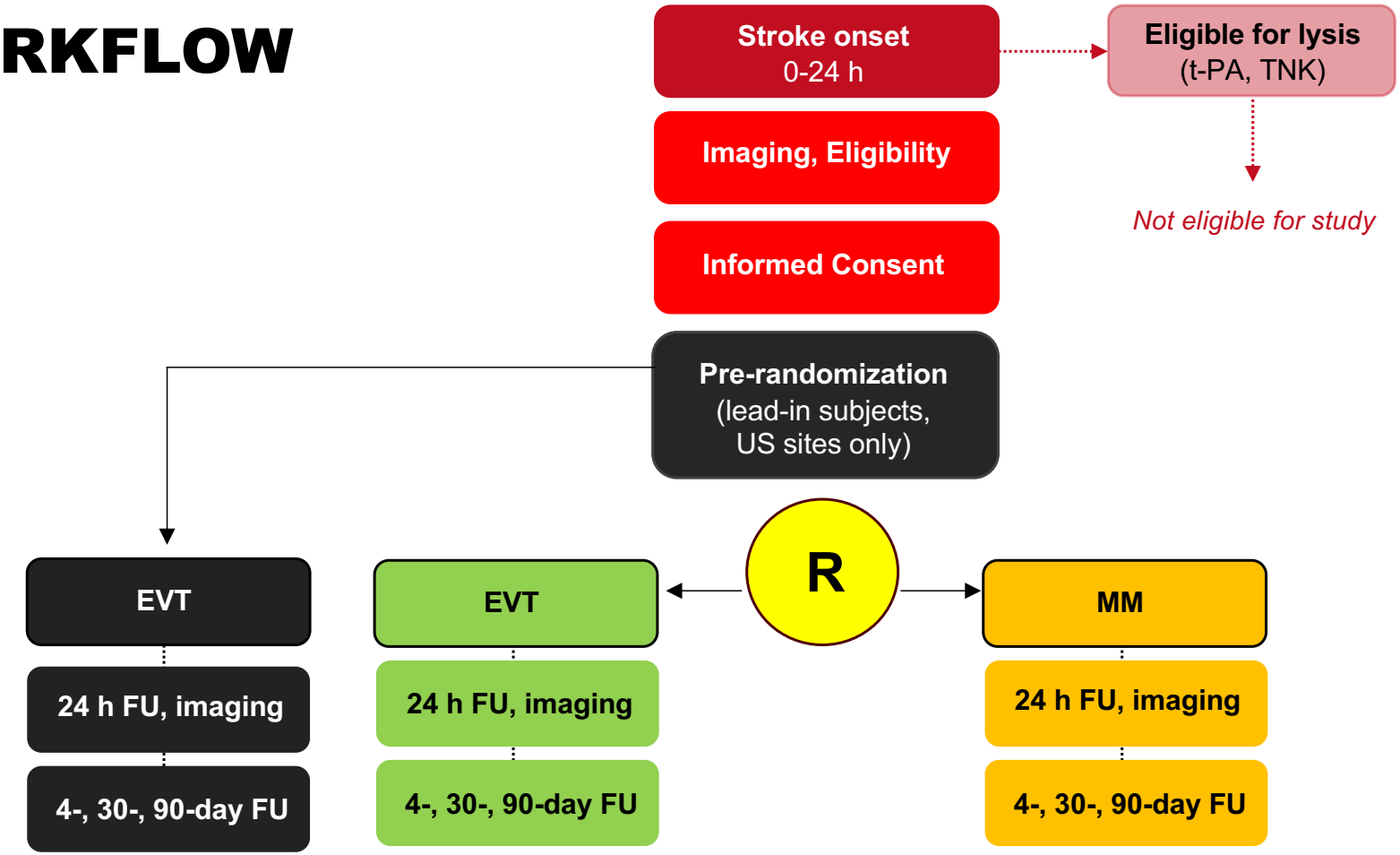
INCLUSION CRITERIA

1. Age 18-85 years old
2. Pre-stroke mRS ≤2
3. Disabling presenting deficits that localize to the territory of the distal vessel occlusion
4. **NIHSS 4-24, or NIHSS 2-24** for patients with aphasia and/or hemianopia
5. Perfusion lesion (Tmax >4.0 seconds) volume ≥10 cc on CTP or MR PWI within **non-/co-dominant M2 MCA, M3 MCA, ACA, or PCA**
6. Occluded distal vessel diameter ≥1.5 mm as measured on CTA or MRA
7. **Ischemic core** (rCBF<30% CTP or ADC <620 DWI) **≤50% of perfusion lesion volume**
8. Study treatment can be initiated **within 24 hours of last known well**
9. Signed informed consent by patient or legally authorized representative
10. **Subject is not eligible for intravenous thrombolysis**

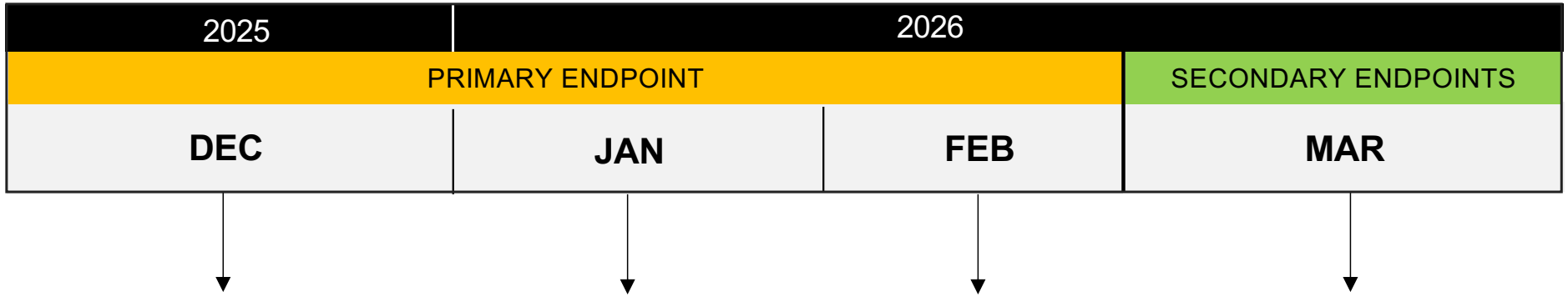
MAJOR EXCLUSION CRITERIA

1. Acute brain hemorrhage on CT and/or MRI at admission.
2. Excessive tortuosity or stenosis that prevents placement of the microcatheter in the target vessel (on CTA or MRA prior to randomization).
3. Tandem occlusion in the cervical/intracranial ICA, M1 MCA, dominant M2 MCA, VA, BA on CTA or MRA.
4. Stroke in the last 3 months.
5. Warfarin treatment with INR >1.7
6. Direct oral anticoagulant (DOAC) treatment within 48 hours
7. Treatment with heparin within 48 hours with a PTT >2X normal.

WORKFLOW


Stroke onset
0-24 h
Eligible for lysis
(t-PA, TNK)
Not eligible for study
Imaging, Eligibility
Informed Consent
Pre-randomization
(lead-in subjects,
US sites only)
R
EVT
24 h FU, imaging
4-, 30-, 90-day FU
EVT
24 h FU, imaging
4-, 30-, 90-day FU
MM
24 h FU, imaging
4-, 30-, 90-day FU

TRIAL STATUS



Last patient enrolled
December 7, 2025

Last patient 24h 1^0 endpoint assessed (*Successful reperfusion without sICH)*
December 8, 2025

Database lock through 1^0 endpoint
January 16, 2026

Primary endpoint results reported
February 6, 2026

Last patient 3-month secondary endpoint visit
March 2026

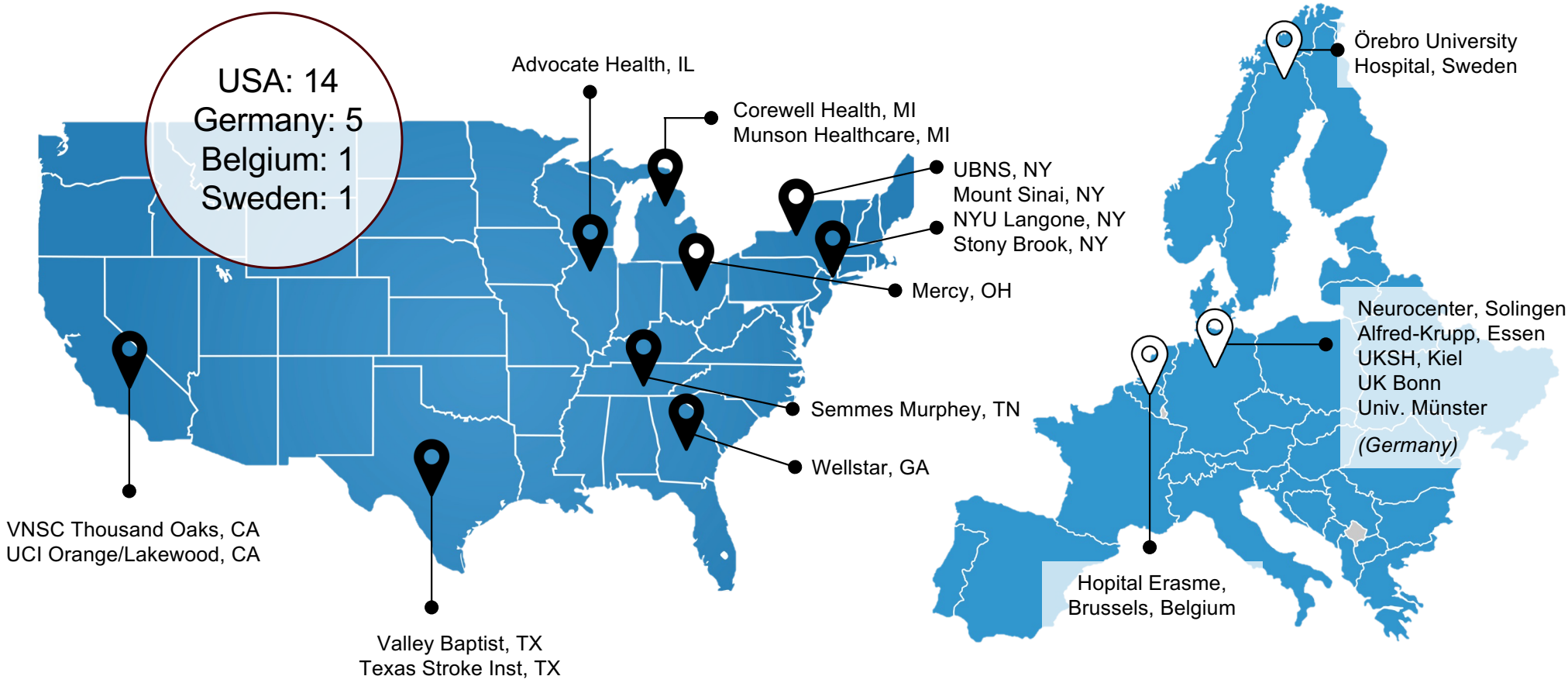
Secondary endpoint results reported
Future presentation (2026)

TRIAL UPDATES

- **Primary endpoint data will be presented**
  - Successful reperfusion: >50% reduction in substantial hypoperfusion (Tmax >4 seconds) volume, without sICH, at 24 hours
  - sICH within 24 hours
- **3-month data** including mRS, quality of life, etc. will be presented following completion of all 3-month follow-up visits

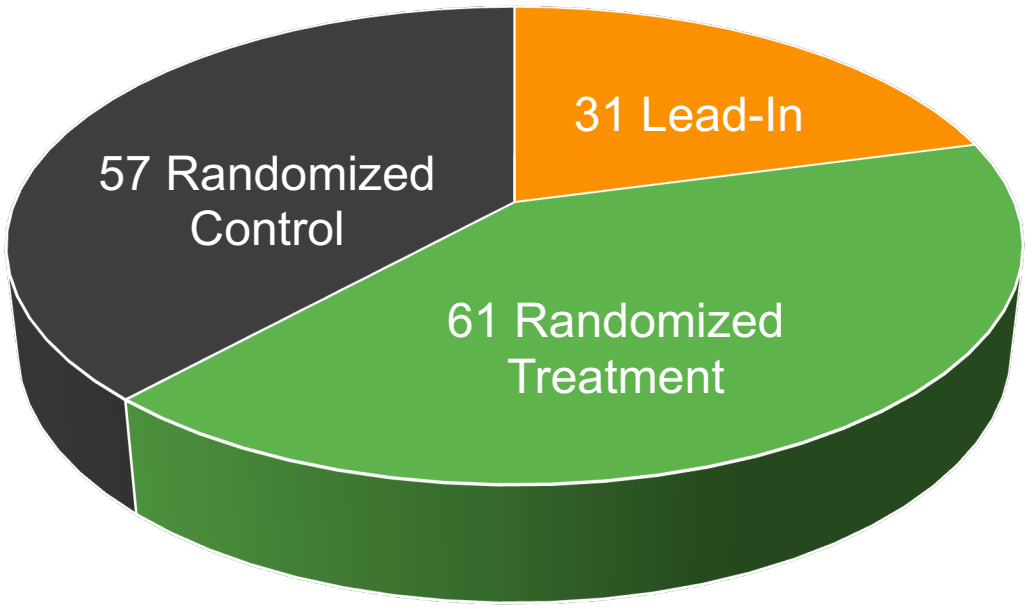
RESULTS

DISTALS' SITES



ENROLLMENT FLOW

Screened	~ 2400
Enrolled	149
Lead in	31
Randomized	118
Treatment Arm	61
Control Arm	57
First patient enrolled	May 2022
Last patient enrolled	December 2025
Last 90 d FU	March 2026



TRIAL DEMOGRAPHICS

Demographics	Randomized: Treatment (n=61)	Randomized: Control (n=57)
Age, mean (SD)	70 (10.6)	68 (11.9)
Sex, male %	59%	63%
NIHSS		
Median (IQR)	6 (4-9)	6 (4-9)
Mean (SD)	7.1 (4.6)	6.8 (4.5)
Median (IQR)	6 (4-9)	6 (4-9)
Pre-stroke mRS, %		
0	81.9%	75.4%
1	4.9%	10%

MEDICAL HISTORY

Comorbidities, % (n)	Randomized: Treatment (n=61)	Randomized: Control (n=57)
Previous stroke / TIA	20% (12)	28% (16)
Previous MI / CAD	15% (9)	16 (9)
Hypertension	72% (44)	77% (44)
Atrial Fibrillation	26% (16)	23% (13)
Diabetes Mellitus	43% (26)	25% (14)
Dyslipidemia	51% (31)	47% (27)
Cocaine use	0%	2% (1)
Cancer with metastases	3% (2)	2% (1)

TARGET OCCLUSION

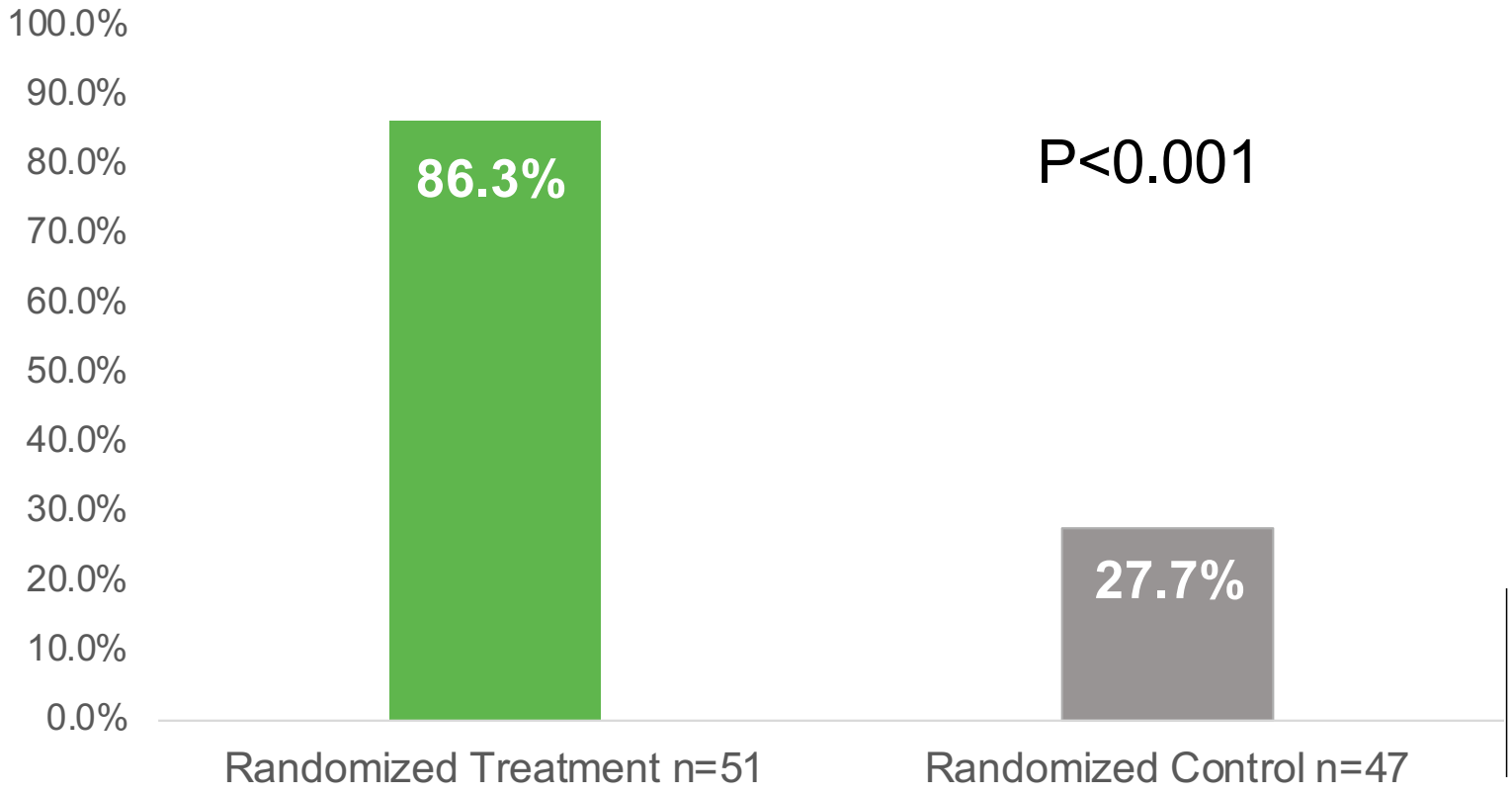
Target Vessel	Randomized: Treatment (n=61)	Randomized: Control (n=57)
M2 MCA	**37.7% (23)**	**43.9% (25)**
Co-dominant M2	21.3% (13)	19.3% (11)
Non-dominant M2	16.4% (10)	24.6% (14)
M3 MCA	**23.0% (14)**	**24.6% (14)**
ACA	**8.2% (5)**	**8.8% (5)**
A1	1.6% (1)	(0)
A2	4.9% (3)	7.0% (4)
A3	1.6% (1)	1.8% (1)
PCA	**31.2% (19)**	**22.8% (13)**
P1	11.5% (7)	10.5% (6)
P2	16.4% (10)	10.5% (6)
P3	3.3% (2)	1.8% (1)

WORKFLOW AND PROCEDURAL DATA

	Randomized: Treatment (n=61)	Randomized: Control (n=57)
LKW to Randomization (min)		
Median (IQR)	548 (270-815)	420 (208-904)
Mean (SD)	591 (362)	549 (392)
Vessel Diameter (mm)		
Mean (SD)	1.8 (0.3)	1.8 (0.3)
Range	1.5-3	1.5-3.1
Anesthesia Type, %		
General Anesthesia	69.5%	n/a
Local	11.9%	n/a
Other	18.6%	n/a

PRIMARY ENDPOINT

Efficacy and Safety Composite – Successful reperfusion at 24 hours without sICH



Data is not evaluable for 20 patients (10 Treatment; 10 Control), perfusion either not done or imaging with poor quality; results robust with multiple imputation and worst-case sensitivity analyses.

PRIMARY ENDPOINT COMPONENTS

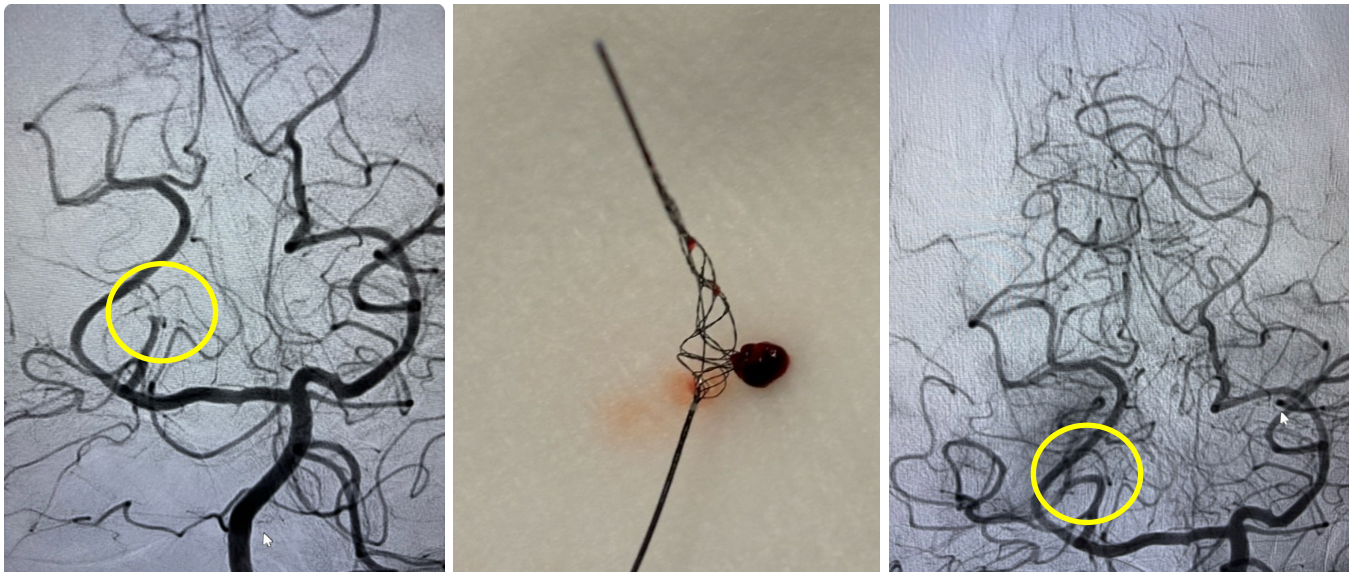
	Treatment (N=51)	Control (N=47)	P Value
Successful reperfusion	86.3%	27.7%	P <0.001
sICH within 24 hours *Treated with Tigertriever 13*	0%	N/A	
sICH within 24 hours *ITT*	1.6%*	0	NS

* One sICH occurred in Treatment subject who was erroneously treated with a commercial device, not Tigertriever 13

EXAMPLE CASE

NIHSS=2 with Hemianopia

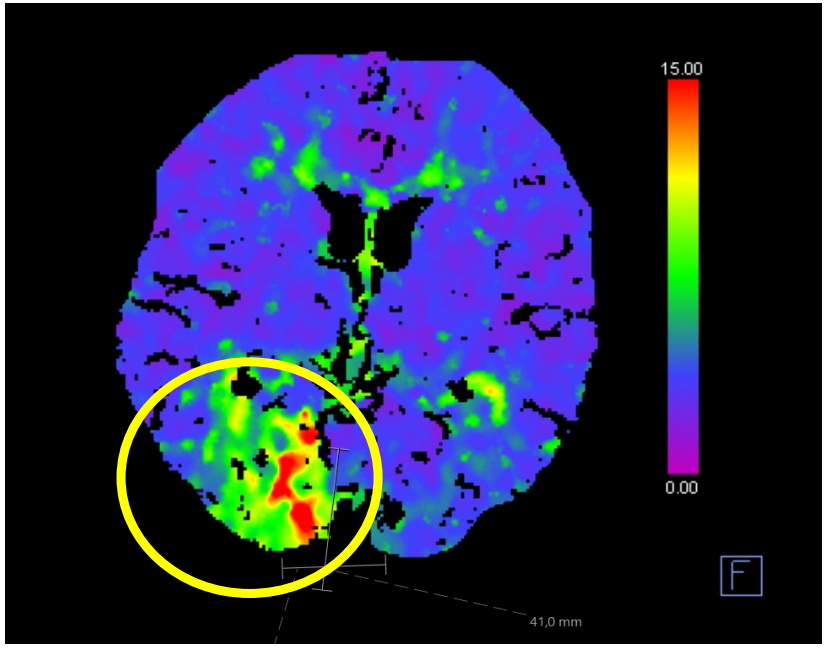
- **68 year old, Female**
- **P3 occlusion**
- **At admission:**
  NIHSS=2, hemianopia
- **Procedure:**
  1 pass, mTICI=3
- **No symptoms at discharge**
  NIHSS=0



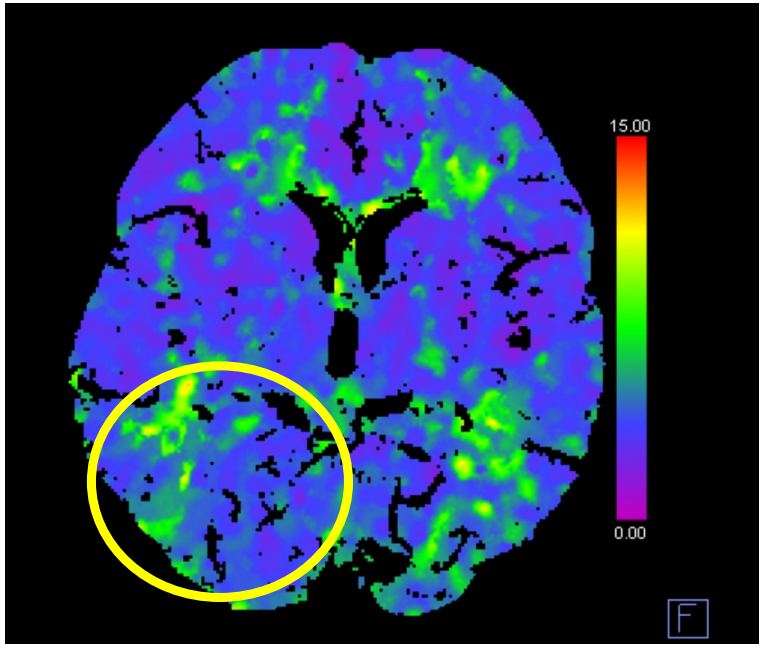
Pre

Post

CT PERFUSION



R P3 BL Tmax



R P3 24h Tmax

DISCUSSION

	DISTAL		ESCAPE-MeVO		DISCOUNT		DISTALS	
Geography	Europe		N America, Europe, Asia		France		N America, Europe	
Devices	Commercial SR & Aspiration		Solitaire X		Commercial SR & Aspiration		Tigertriever 13	
RESULTS	**Control**	**EVT**	**Control**	**EVT**	**Control**	**EVT**	**Control**	**EVT**
N	272	271	274	255	80	81	57	61
Age (years)	77	77	76	74	72	75	68	70
Female	45%	43%	46%	46%	48%	46%	37%	41%
NIHSS	6 (5-9)	6 (5-9)	7 (5-11)	8 (6-11)	8 (6-12)	8 (6-11)	6 (4-9)	6 (4-9)
IV lytic	69%	62%	60.2%	56.5%	71%	70%	0%	0%
M2	40.4%	47.6%	36.8%	50.2%	75% (M2+M3)	76% (M2+M3)	43.9%	37.7%
M3	30.9%	22.9%	46.8%	35.6%			24.6%	23%
ACA	4.0%	7.4%	4.4%	4.8%	8%	7%	10.6%	6.5%
PCA	23.9%	18.1%	9.9%	9.5%	18%	17%	22.8%	31.2%
Onset to Rand (min)	240	228	253	270	270	240	420	548
eTICI 2b-3 (Final)	n/a	71.7%	n/a	75.1%	n/a	77%	n/a	pnd
Reperfusion @ 24hrs	n/a	n/a	n/a	n/a	n/a	n/a	28%	86%
sICH	2.6%	5.9%	2.2%	5.4%	6%	12%	0	1.6%

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CONCLUSIONS

1. **DISTALS trial enrolled a distinctive DMVO population**
    - Younger
    - No IV lytics or anticoagulants
    - Later after onset
2. **Sustained reperfusion at 24h achieved in 8.5 of every 10 EVT patients**
    - Compared with 2.8 of every 10 MM patients
3. **No sICH occurred in the EVT group using Tigertriever 13**
4. **Trial positive on primary endpoint of reperfusion w/o sICH**
    - 3 month clinical outcomes still being collected and will be reported in future
5. **T13 is a safe and effective clot removal treatment strategy for DMVO patients**
    - Unique design of T13 provides safe navigation and retrieval

THANK YOU DISTALS INVESTIGATORS

René Chapot	*Alfried-Krupp Krankenhaus, Essen, Germany*
Hannes Nordmeyer	*Neurocenter, Solingen, Germany*
Olav Jansen	*University Hospital Schleswig-Holstein, Kiel, Germany*
Franziska Dorn	*Universitatsklinikum, Bonn, Germany*
Paul Stracke	*Universität Münster, Münster, Germany*
Noemie Ligot	*Hopital Erasme, Brussels, Belgium*
Hozan Radhi	*Örebro University Hospital | USÖ, Sweden*
Ahmad Khaldi	*WellStar, Marietta, GA*
Adnan Siddiqui	*UBNS, Buffalo, NY*
Asif Taqi	*Los Robles, Thousand Oaks, CA*
Eugene Lin	*Mercy, Toledo, OH*
Ameer Hassan	*Valley Baptist, Harlingen, TX*
David Fiorella	*Stony Brook University, Stony Brook, NY*
Hazem Shoirah	*Mount Sinai, New York, NY*
Erez Nossek	*NYU Langone New York, NY*
Albert Yoo	*Texas Stroke Institute, Plano, TX*
Paul Mazaris	*Corewell Health, Grand Rapids, MI*
Demetrius Lopes	*Advocate Health, Chicago, IL*
Radoslav Raychev	*UCI, Orange/Lakewood, CA*
Lucas Elijovich	*Semmes-Murphey, Memphis, TN*
David Rosenbaum	*Munson Medical Center, Traverse City, MI*

THANK YOU

International Stroke Conference

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