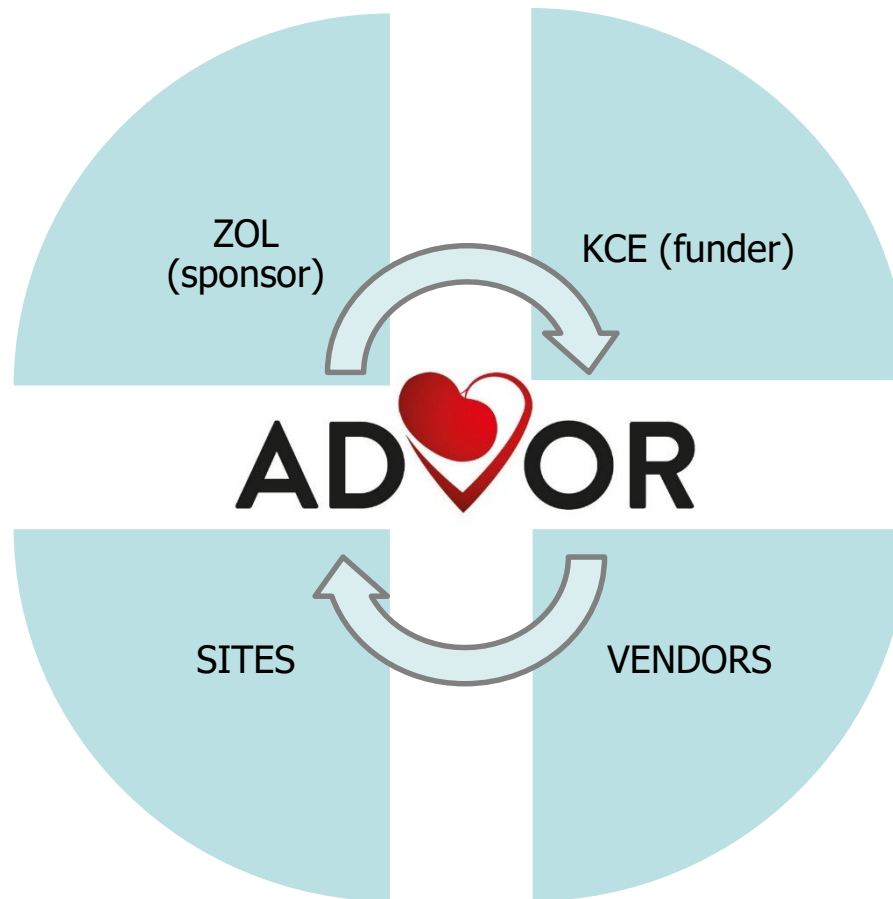




Online Status Meeting

23 February 2021

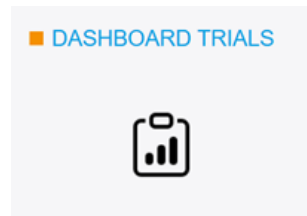
Introduction



KCE dashboard



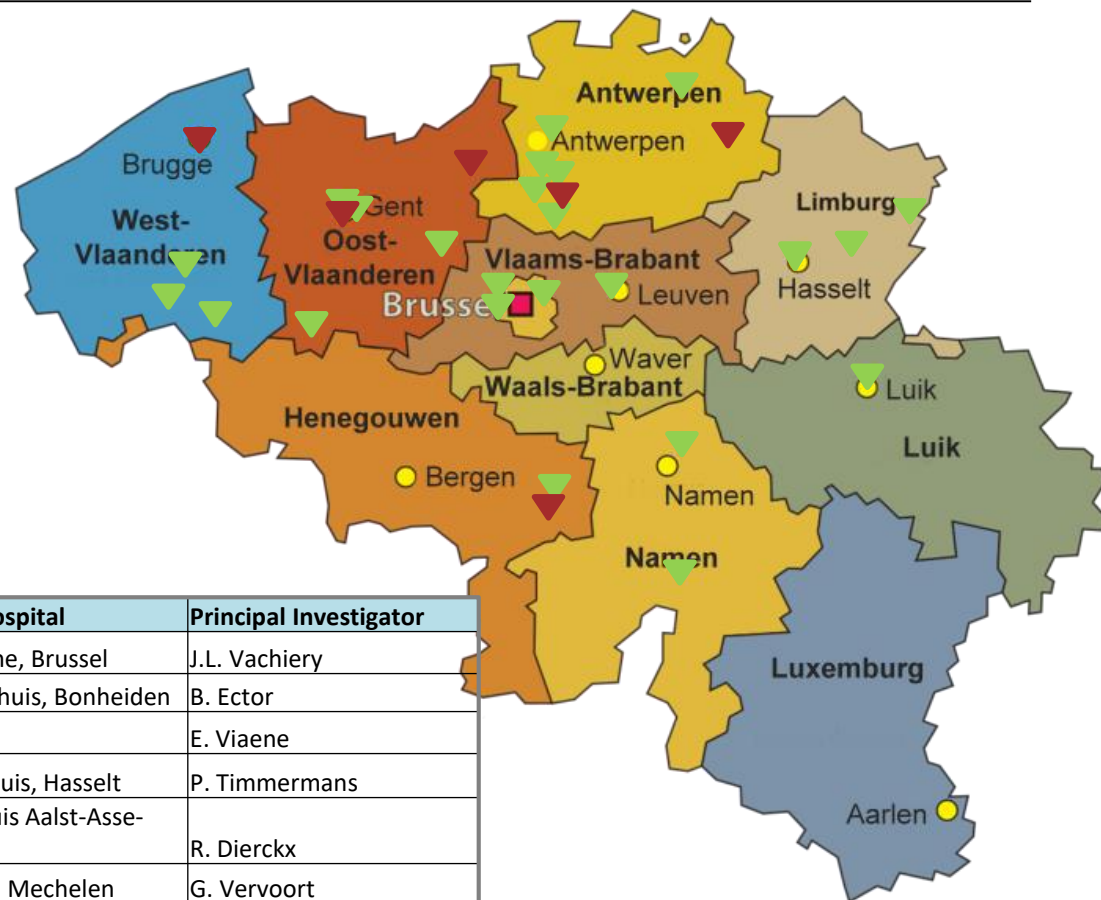
<https://kce.fgov.be/>



<https://trials.kce.be/dashboard/>

29 Active sites

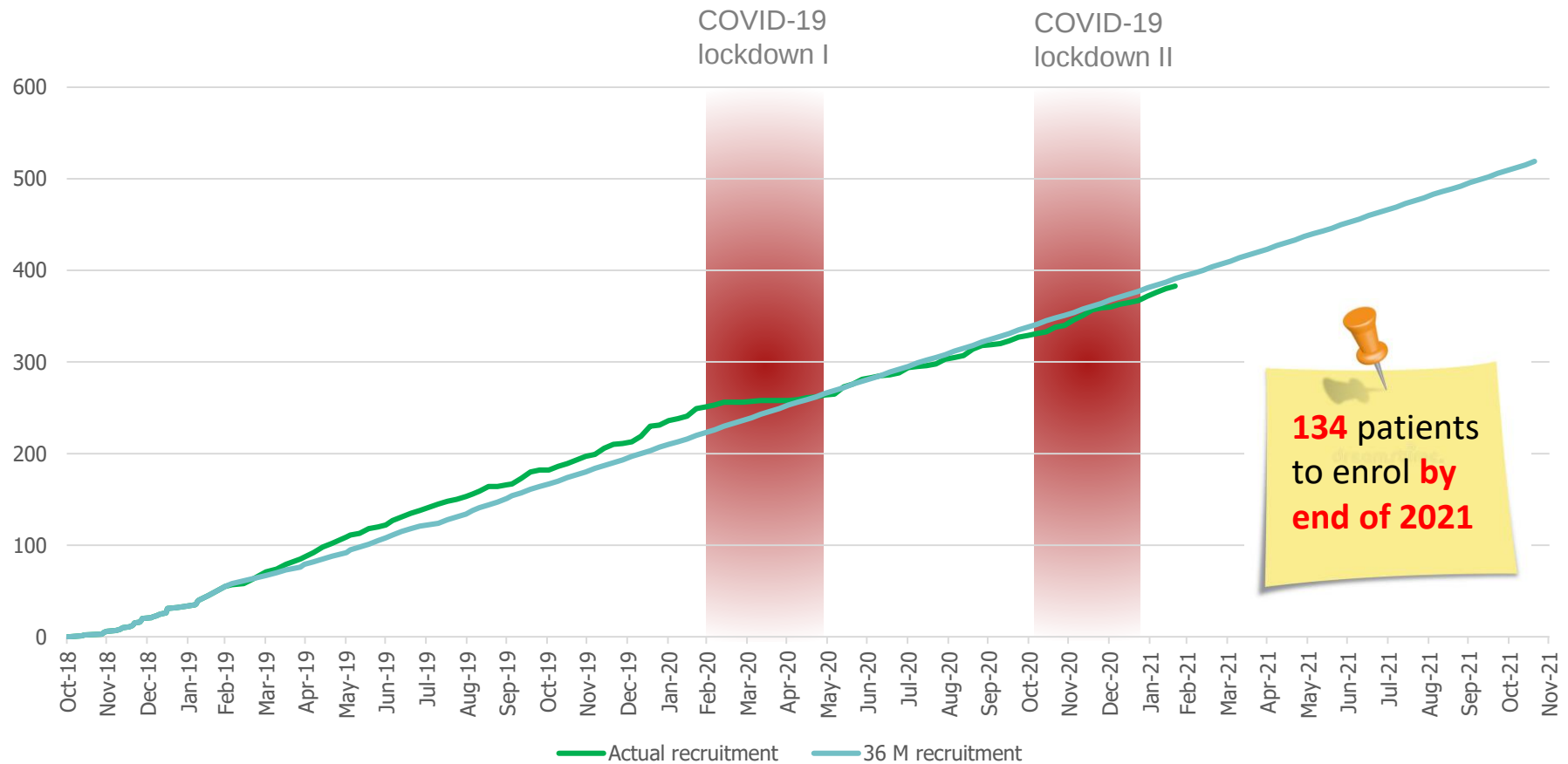
Hospital	Principal Investigator
AZ Delta Roeselare-Menen	M. Deceunick
AZ Glorieux, Ronse	F. Van Durme
AZ Groeninge, Kortrijk	D. Derthoo
AZ klina, Antwerpen	W. Smolders
AZ Maria Middelaes Gent	D. Vervloet
AZ Mol	H. Striekwold
AZ Nikolaas, St-Niklaas	K. Goossens
AZ Sint-Lucas, Gent	H. Vandekerckhove
AZ Turnhout	P.J. Hofkens
CHR de la Citadelle, Luik	P. Troisfontaines
CHU Charleroi	S. Moubayed
CHU UCL Namur	L. Gabriel
Clinique Saint-Luc Bouge	P. Blouard
Grand Hôpital de Charleroi	F. Chenot
GZA, sint-Vincentius, Wilrijk	D. Raes



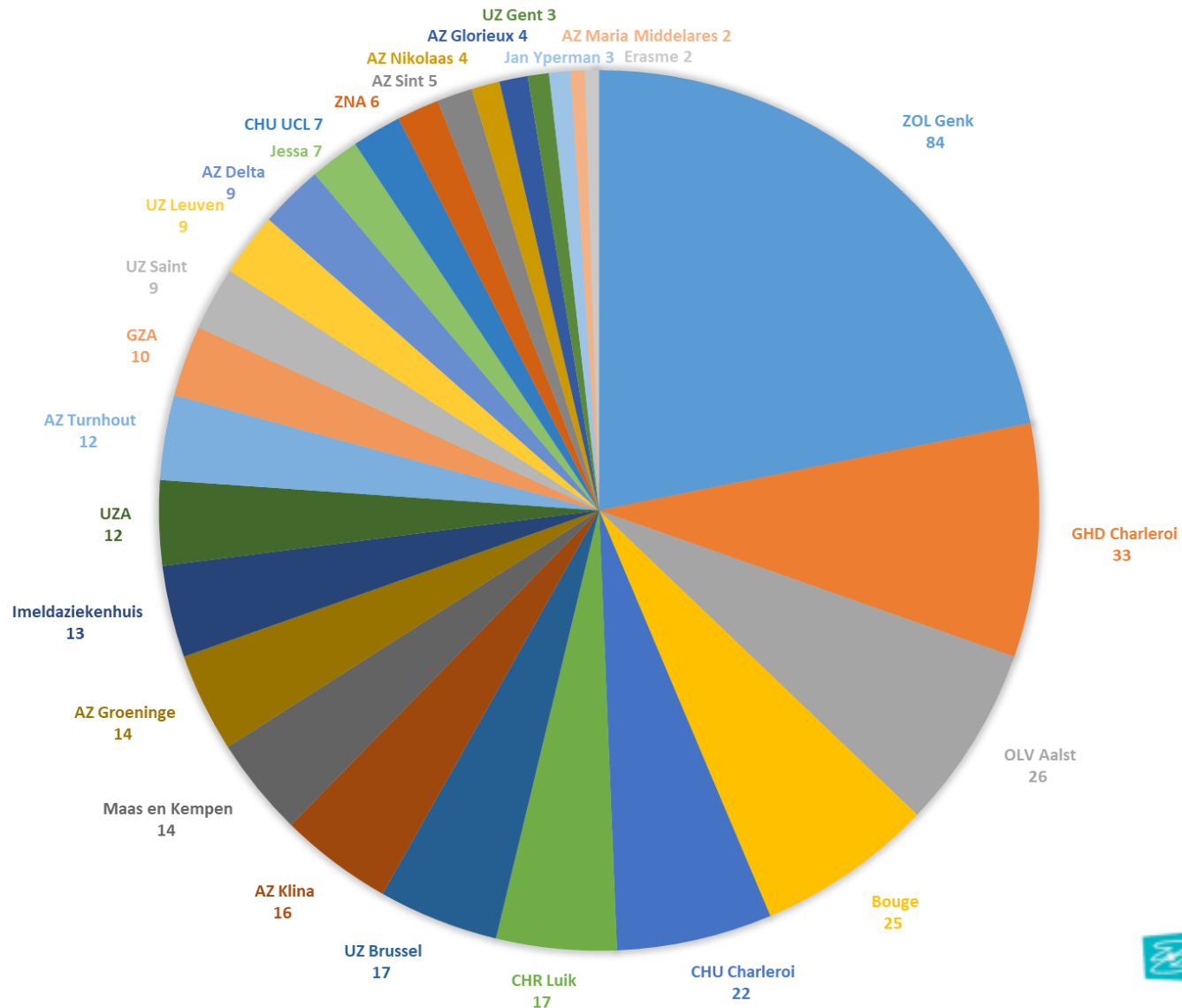
Hospital	Principal Investigator
Hôpital Erasme, Brussel	J.L. Vachiery
Imeldaziekenhuis, Bonheiden	B. Ector
Jan Yperman	E. Viaene
Jessa Ziekenhuis, Hasselt	P. Timmermans
OLV Ziekenhuis Aalst-Asse-Ninove	R. Dierckx
Sint Maarten, Mechelen	G. Vervoort
UZ Antwerpen	E. Van Craenenbroeck
UZ Brussel	S. Lochy
UZ Gent	M. Depauw
UZ Leuven	W. Drooghe
UZ Saint-Luc, Brussel	A.C. Pouleur
Ziekenhuis Maas en Kempen	M. Hulselmans
Ziekenhuis Oost Limburg AV	W. Mullens
ZNA Middelheim	E. Prihadi

ADVOR patient recruitment

Recruitment update 22 February 2021: **385** patients enrolled



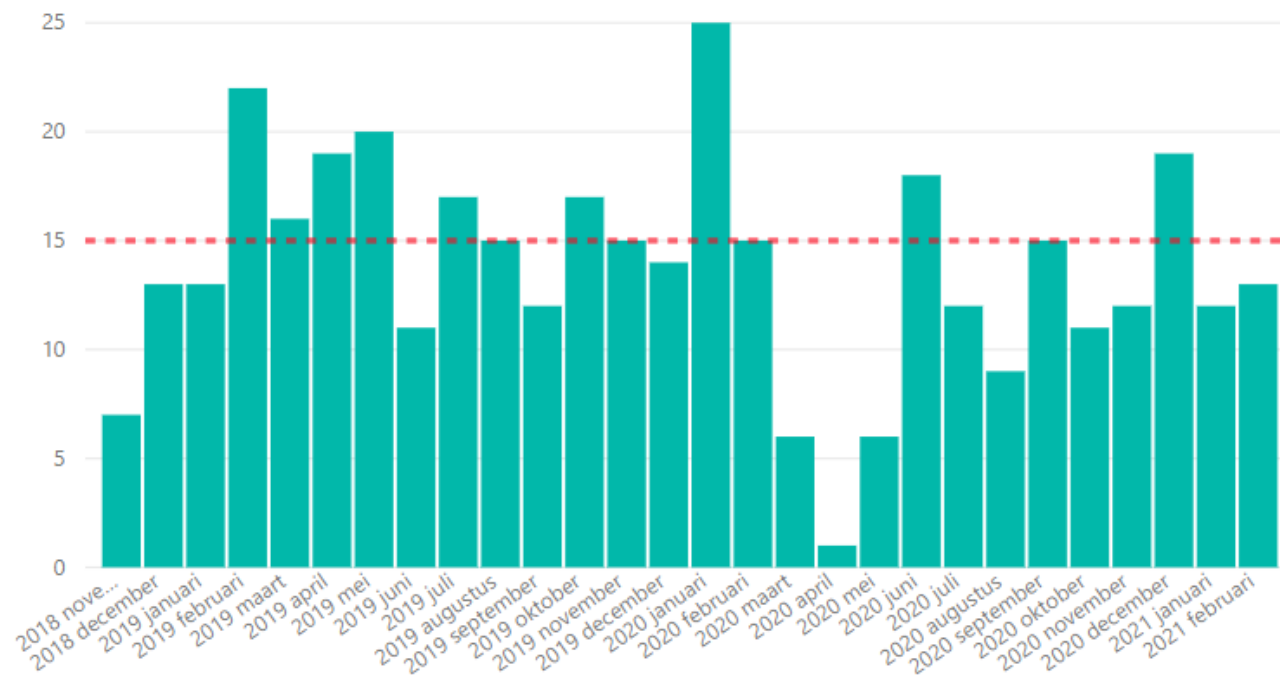
ADVOR patient recruitment – per center



ADVOR patient recruitment feasibility

2018 – 20 patients
2019 – 191 patients
2020 – 149 patients
2021 – **159 patients**
(25 pts already enrolled)

Total randomized patients per month:



ADVOR patient recruitment – per center

Hospital	Day	Month	Year	Total number of patients enrolled	Average number of patients enrolled per month
GHD Charleroi	22	February	2021	33	1,3
CHU Charleroi	22	February	2021	22	1,8
Bouge	19	February	2021	25	1,0
Maas en Kempen	17	February	2021	14	0,5
ZOL Genk	16	February	2021	84	3,1
GZA	10	February	2021	10	0,4
OLV Aalst	9	February	2021	26	1,0
ZNA	4	February	2021	6	0,3
AZ Klina	3	February	2021	16	0,7
AZ Groeninge	25	January	2021	14	0,6
UZA	7	January	2021	12	0,5
Imeldaziekenhuis	4	January	2021	13	0,5
CHR Luik	8	December	2020	17	0,7
AZ Sint	7	December	2020	5	0,4
AZ Nikolaas	30	November	2020	4	0,3
UZ Brussel	21	October	2020	17	0,7
AZ Turnhout	22	September	2020	12	0,4
UZ Saint	22	September	2020	9	0,3
Jessa	24	July	2020	7	0,3
UZ Gent	22	June	2020	3	0,2
AZ Maria Middelaes	3	March	2020	2	0,1
CHU UCL	19	February	2020	7	0,3
UZ Leuven	12	February	2020	9	0,3
AZ Glorieux	11	February	2020	4	0,2
Erasme	15	January	2020	2	0,1
AZ Delta	14	January	2020	9	0,4
Jan Yperman	5	August	2019	3	0,1
Sint Maarten	initiated but no patients enrolled yet				
AZ Mol	initiated but no patients enrolled yet				

How to optimize patient recruitment?



TRAINING

Knowledge
ADVOR protocol



Centralize
patients on **1**
ward

Consultation

Emergency room

Identify
patients

- HF patient
- Need for diuretics

 ADVOR SC

Maximum 2mg Bumetanide IV

! Patient can still be randomized the next day !

Characteristics of 385 enrolled patients

Gender	Average Age	HFpEF	HFrEF	Total
Female	80	107	34	139
Male	77	109	135	244
Total	78	216	169	385

ADVOR website for support and information

ADVOR website: www.advor.be

- Provides an easy overview of inclusion and exclusion criteria
- Provides an update on recruitment
- Gives access to useful links (ALEA randomization system, CASTOR EDC, EDGE, etc.)
- Training material for new study personnel: explanatory video of study protocol and sub-study
- Provides answers on frequently asked questions



advor@zol.be

089 32 73 25



ADVOR Status Data collection & review



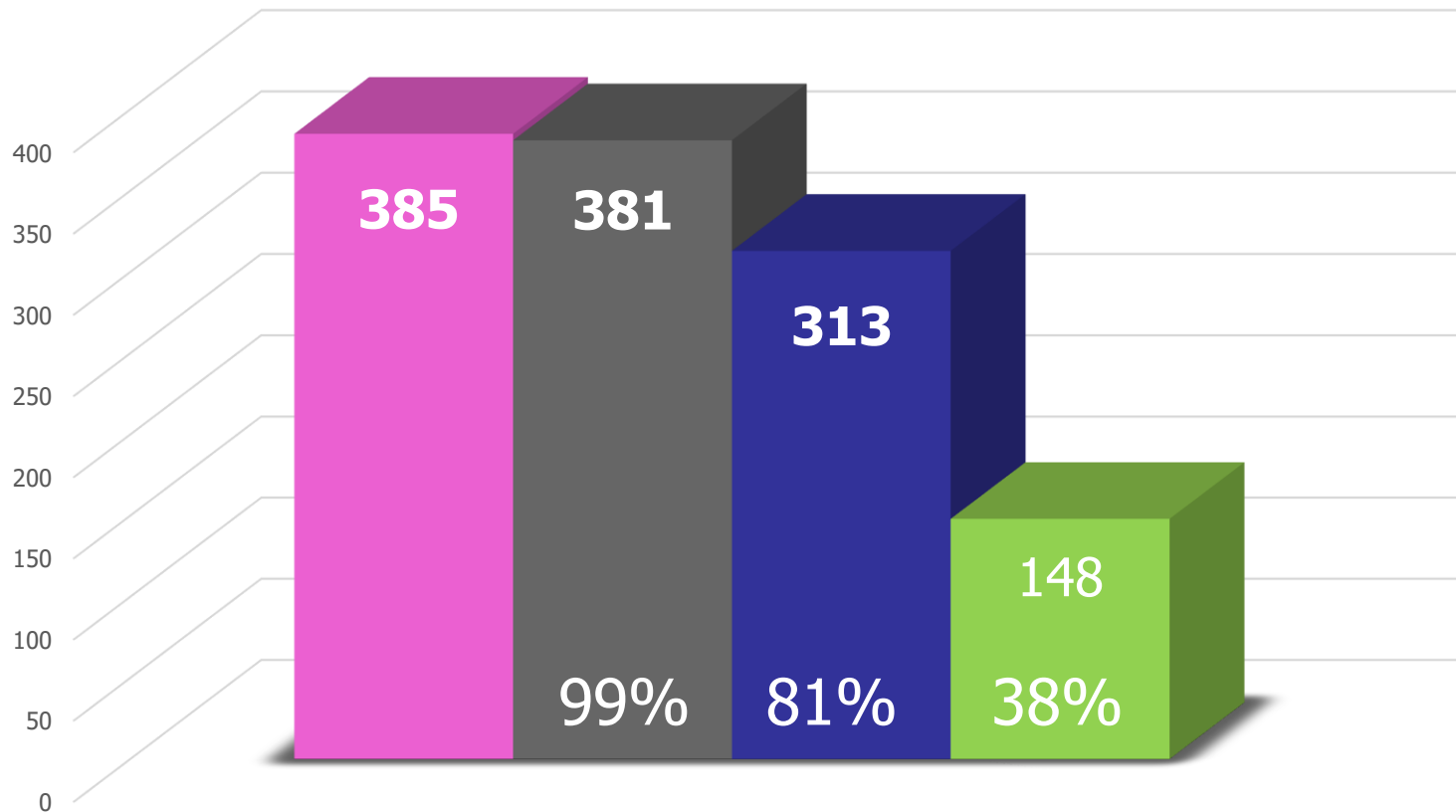
Data entry (e.g. creation of a randomized patient in eCRF)



average of 3 days

ADVOR Status Data collection & review

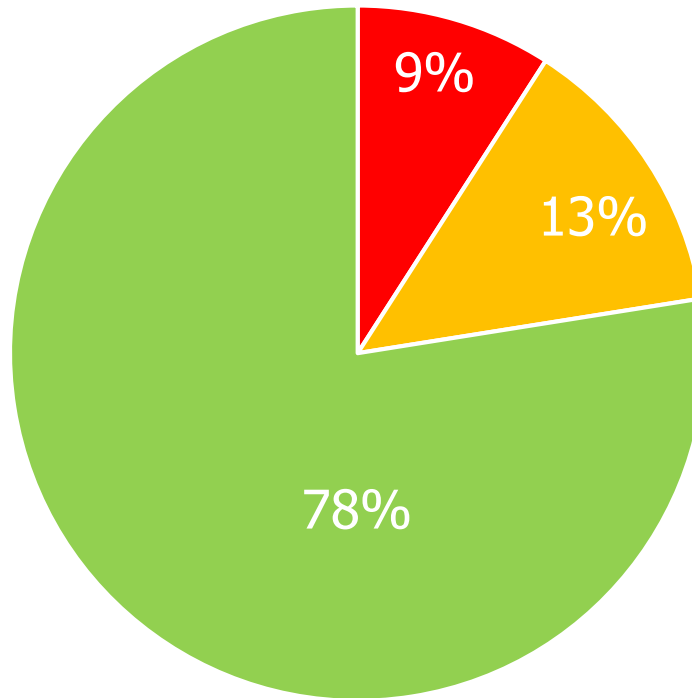
Data Review Status



- Number of enrolled patients
- Number of patients for which data entry started
- Number of patients for which DM review started
- Number of patients for which CRF is locked

ADVOR Status Data collection & review

Query Status



■ Queries open ■ Queries resolved ■ Queries closed

ADVOR Status Protocol Deviations

107 major protocol deviations:

- Eligibility data
 - Use of SGLT2 inhibitor
- Randomization data
 - Different kit number than assigned by ALEA
- Primary endpoint data
 - Escalation therapy not given while urinary output <3500 mL and VA score > 1
- Treatment compliance data
 - More than 10 min between IMP and loop diuretics
 - Less than 6 hours between administrations
 - Treatment not given (not per protocol)
 - Treatment given (not per protocol)

ADVOR Monitoring Status



- ✓ 81 site monitoring visits
- ✓ 287 ICFs
- ✓ 289 Inclusion/Exclusion forms
- ✓ 207 patients SDV I/E forms
- ✓ 202 patients SDV primary endpoint data
- ✓ 139 patients SDV secondary endpoint data



+ COVID-19

=> monitoring plan V2.0: on-site monitoring + remote monitoring



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Together we can do
great things.



EXTRA slides

ADVOR Status Data collection & review



Major Protocol Deviations	107
Eligibility	8
Informed consent procedure	5
Low (NT-pro)BNP	1
Use of SGLT-2 inhibitor	2
Primary endpoint	18
Escalation therapy not given while urinary output <3500 mL and VA score > 1	8
Not all urine collected	1
Urine collection 1 started prior to first treatment administration	7
Volume assessment not done	2
Randomization	1
Received different kitnumber than assigned by ALEA	1
Treatment compliance	80
Less than 6 hours between administrations	14
More than 10 min between IMP and loop diuretics	28
SGLT2 inhibitor during screening/treatment phase	1
Treatment given (not per protocol)	7
Treatment not given (not per protocol)	29
Wrong kit used	1

