STUDIO GEROVAX

VACCINAZIONE ANTI-SARS-COV-2 NELLE STRUTTURE RESIDENZIALI

Monitoraggio clinico- dati finali

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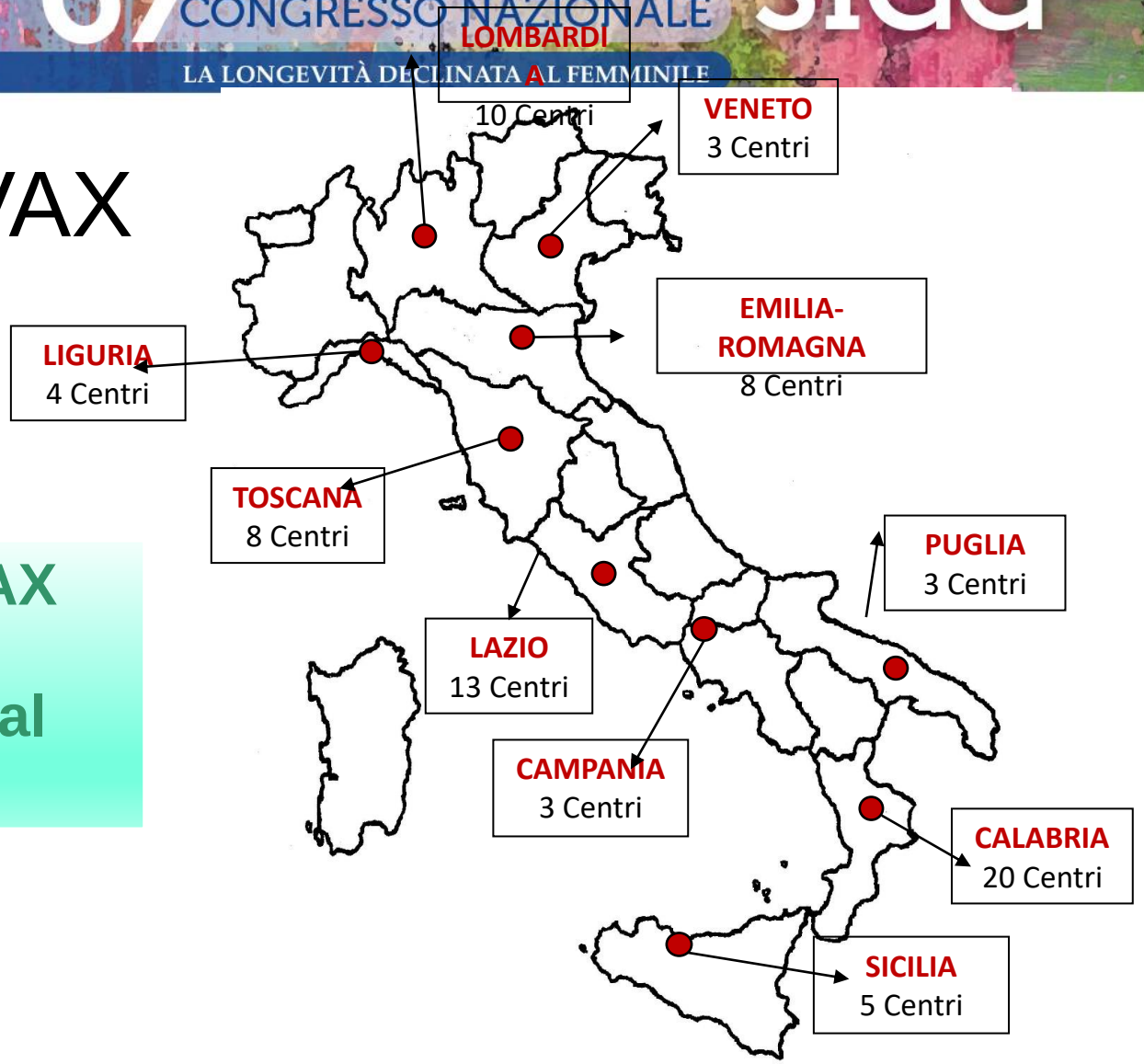
Studio GeroVax - Scopo

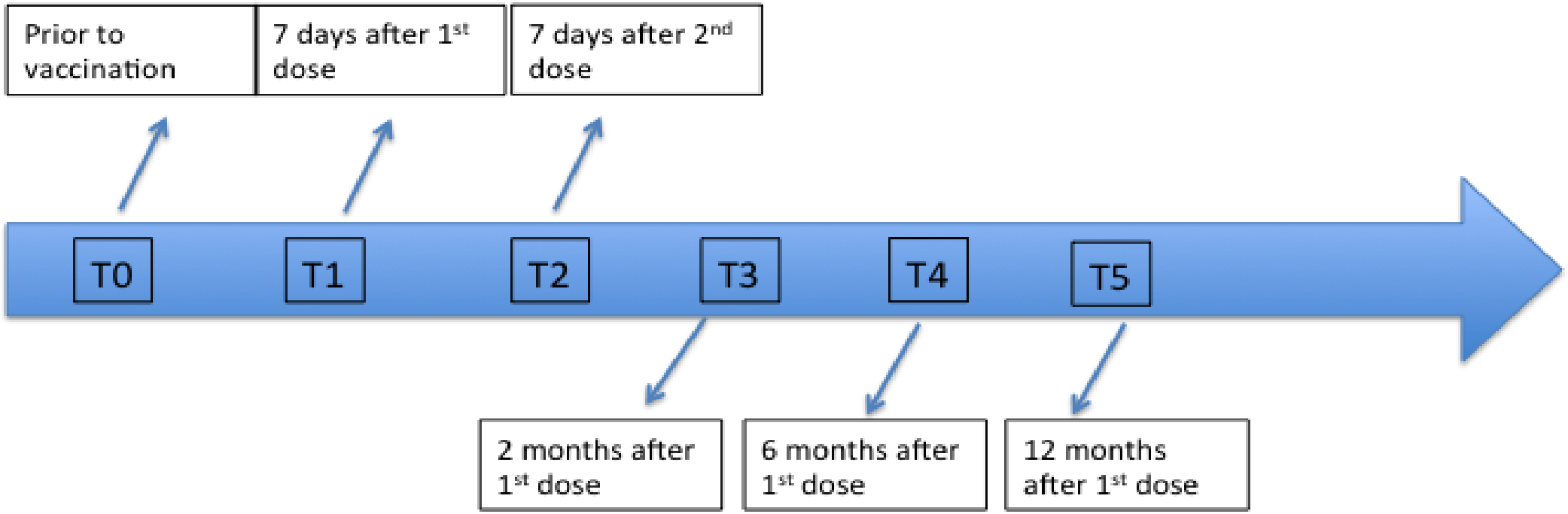
1. Valutare sicurezza ed efficacia clinica della vaccinazione anti-SARS-CoV-2 in RSA (Monitoraggio Clinico)
2. Identificare la risposta cellulare e la durata della protezione indotta dalla vaccinazione attraverso il monitoraggio dell’andamento del titolo anticorpale e della risposta cellulo mediata (Monitoraggio immunologico)

GeroCovid VAX



GeroCovid VAX
Nr. 77
Investigational Sites

Timeline-Clinical Monitoring



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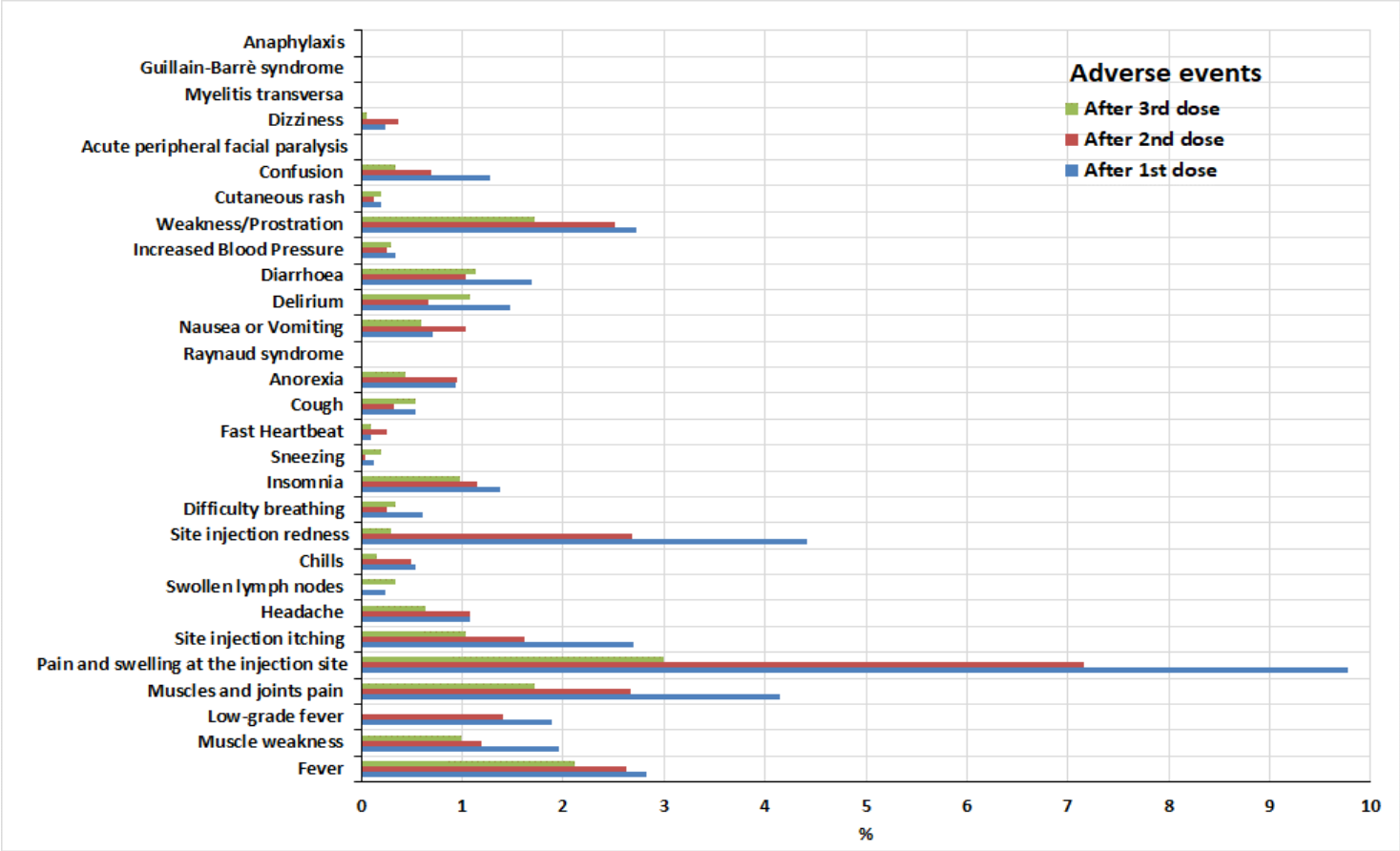
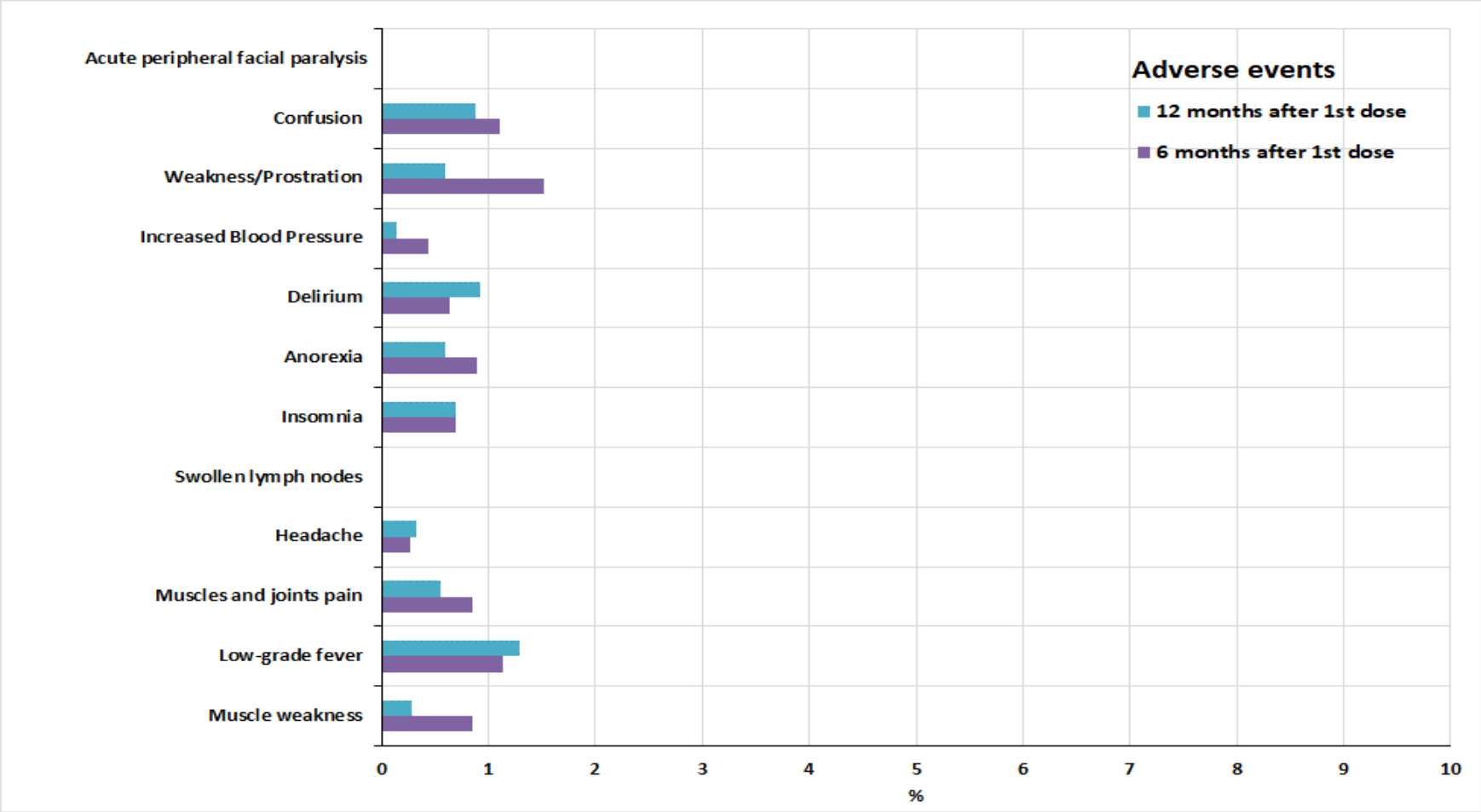
Caratteristiche campione (n=3262)

- ✓ Donne: 71,1%
- ✓ Età Media: 83,4 ± 9,2
- ✓ N di malattie croniche: 5,3 ± 2,5
- ✓ Mobilità
  - > Non cammina autonomamente: 43.9%
  - > Allettato: 14.7%
- ✓ Precedente COVID-19: 30,3%
- ✓ Vaccino SARS-CoV-2
  - > BNT162b2: 93.3%
  - > mRNA-1273: 6.7%

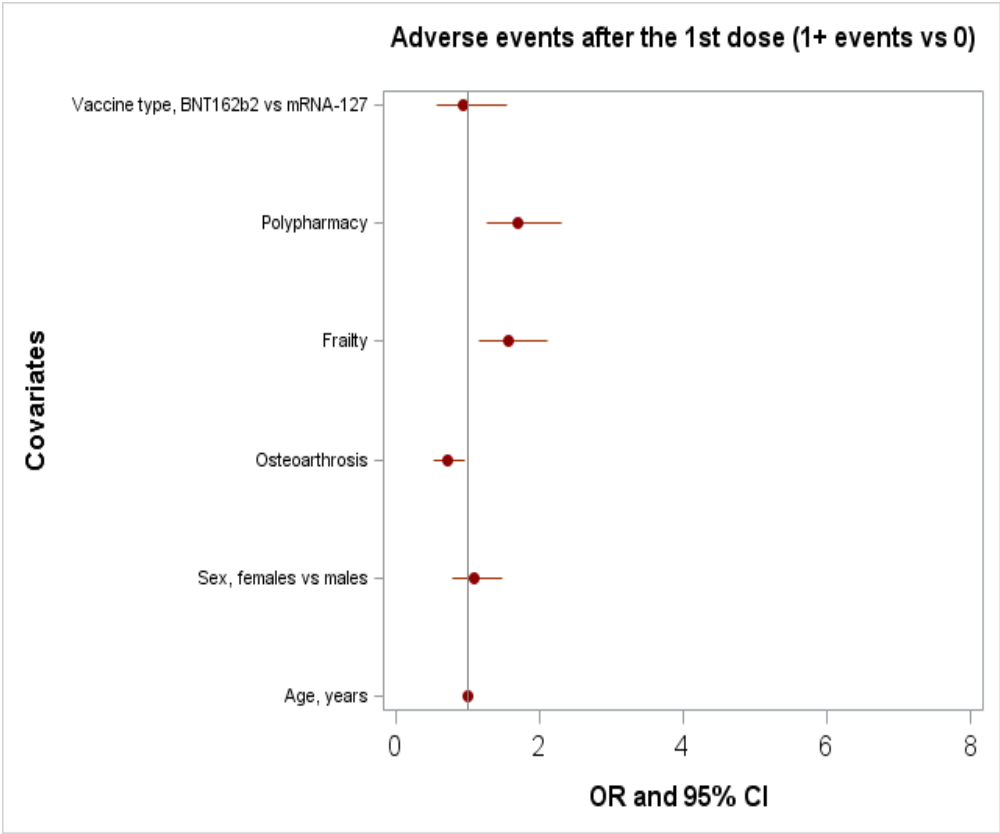
Short-term Adverse events after vaccinations

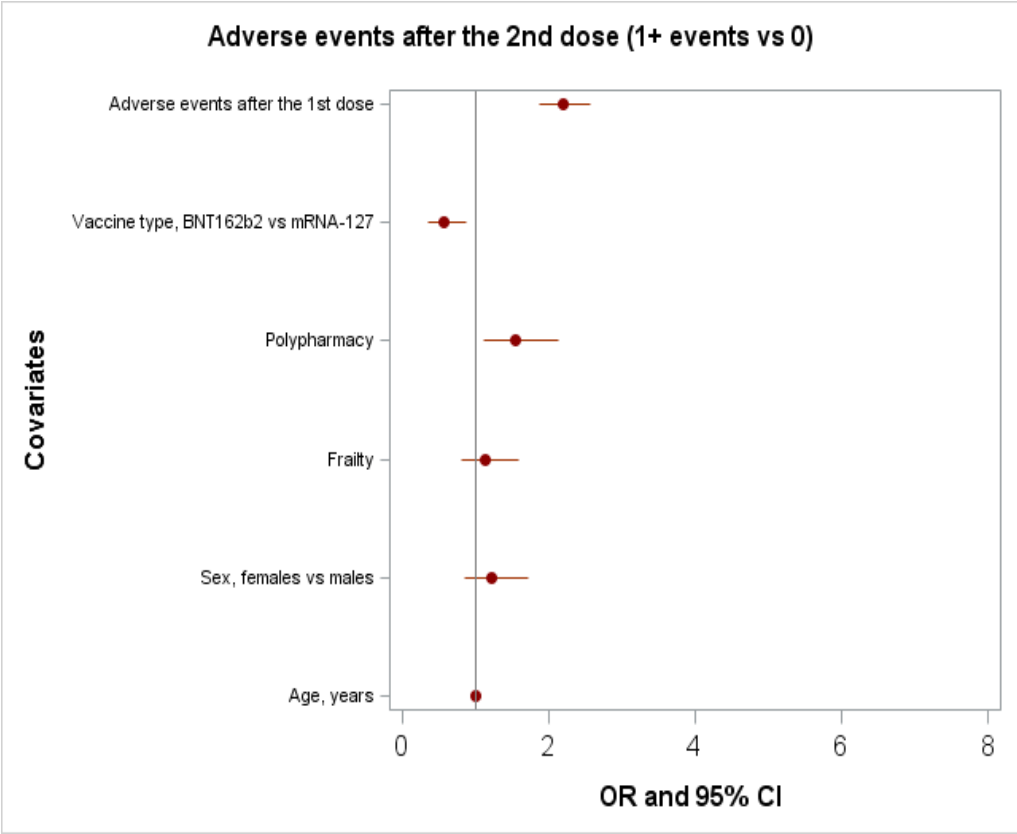


Long-term Adverse Events



Characteristics associated with adverse events





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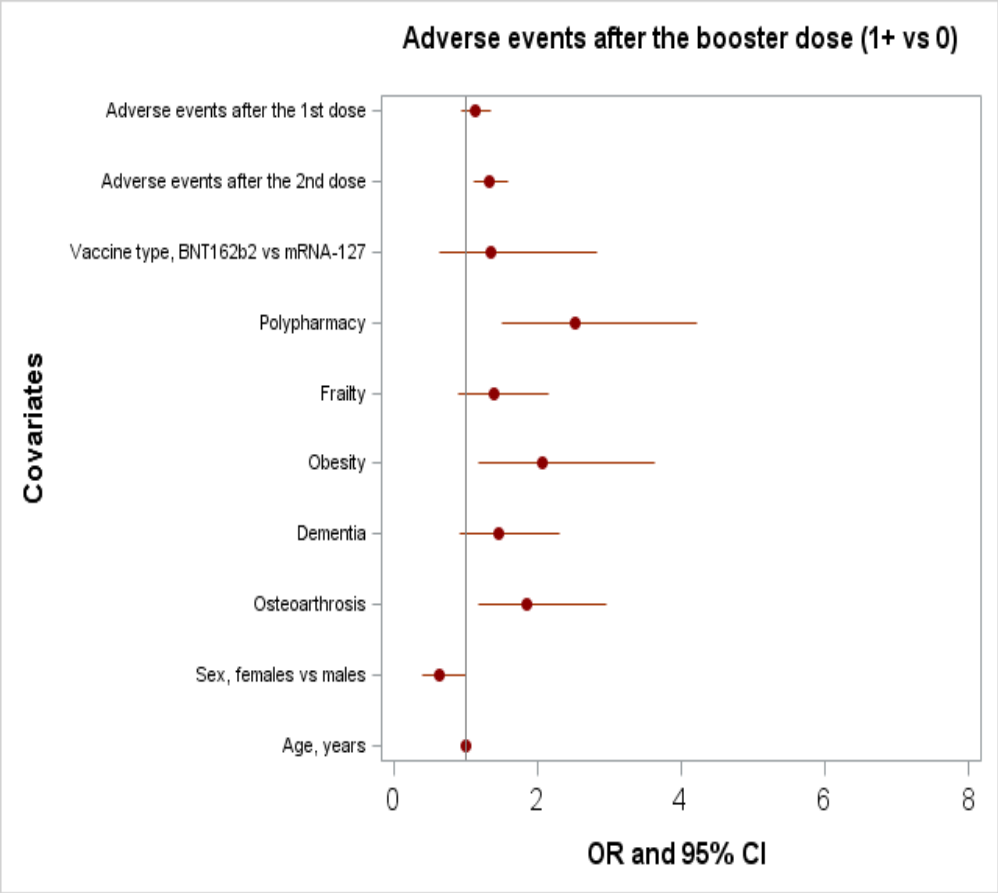
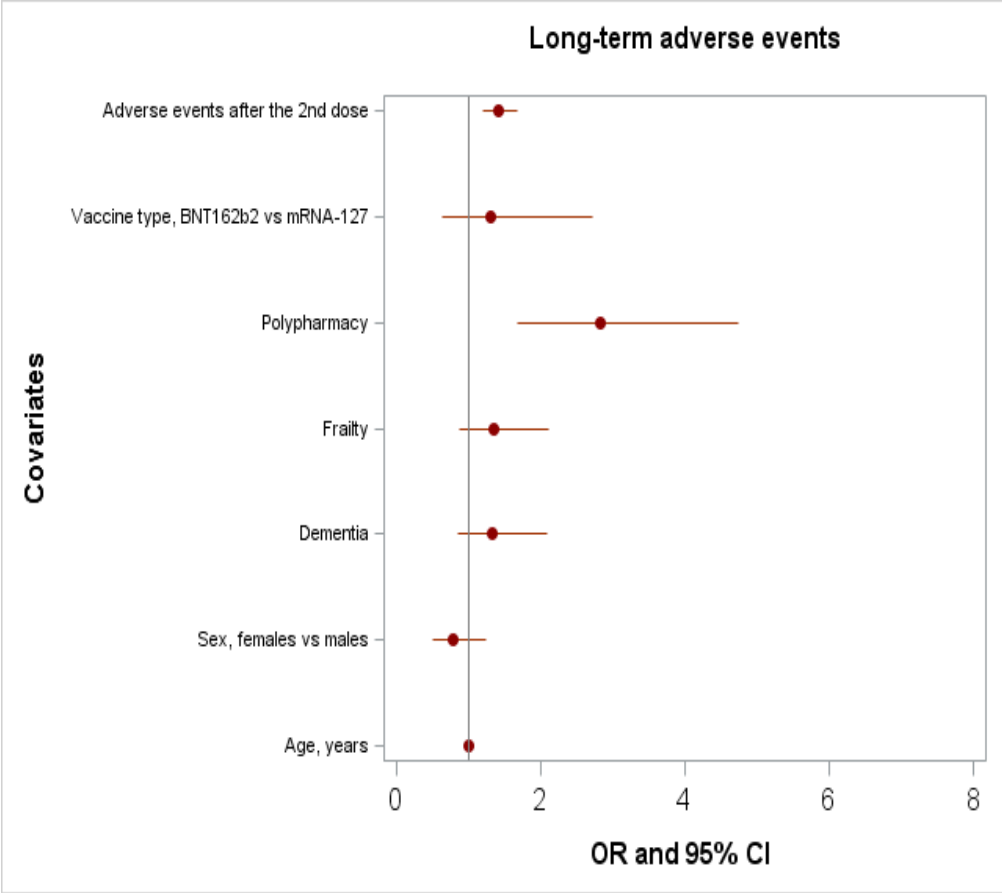




COVID-19 cases

	Before enrollment	Before the 2nd dose (but after enrollment) (a)		After the 2nd dose (but before the booster dose) (b)		After the booster dose (c)		
Time period		**12.2020—03.2021**		**03.2021—12.2021**		**10.2021—05.2022**		
	Number of cases (%)	Number of cases	Incidence rate per 1000 person-years (95% CI)	Number of cases	Incidence rate per 1000 person-years (95% CI)	Number of cases	Incidence rate per 1000 person-years (95% CI)	p-value
Overall	947 (32.9)	129	245.07 (202.78, 287.36)	115	53.21 (43.48, 62.93)	180	78.62 (67.14, 90.11)	a vs b <0.0001 a vs c <0.0001 b vs c 0.0012
Severity, n (%)								
Asymptomatic	516 (56.0)	106 (90.6)		113 (98.3)		171 (95.5)		
Mild-moderate	406 (44.0)	7 (6.0)		2 (1.7)		8 (4.5)		
Severe		0 (0.0)		0 (0.0)		0 (0.0)		
Death		4 (3.4)		0 (0.0)		0 (0.0)		

Frailty

Frailty Anamnestic Criteria

Frailty Anamnestic Criteria (adapted from Pedone et al, 2016, Fried et al, 2001)

1) Exhaustion (fill A or B) Subjective Observed

A. Subjective criterion:

Did the patient in the past months report a feeling of needing an effort to do everything, and was it considered present for more than 3 or 4 days in the week? Yes No Unknown

B. Observed criterion (by the Health Care Professional or reported by a proxy):

2) Unintentional weight loss

Was an unintentional loss of weight recorded at baseline during medical interview and was it defined as a reduction in weight more than 4.5 kg in the past 12 months? Yes No Unknown

3) Reduced Physical Activity

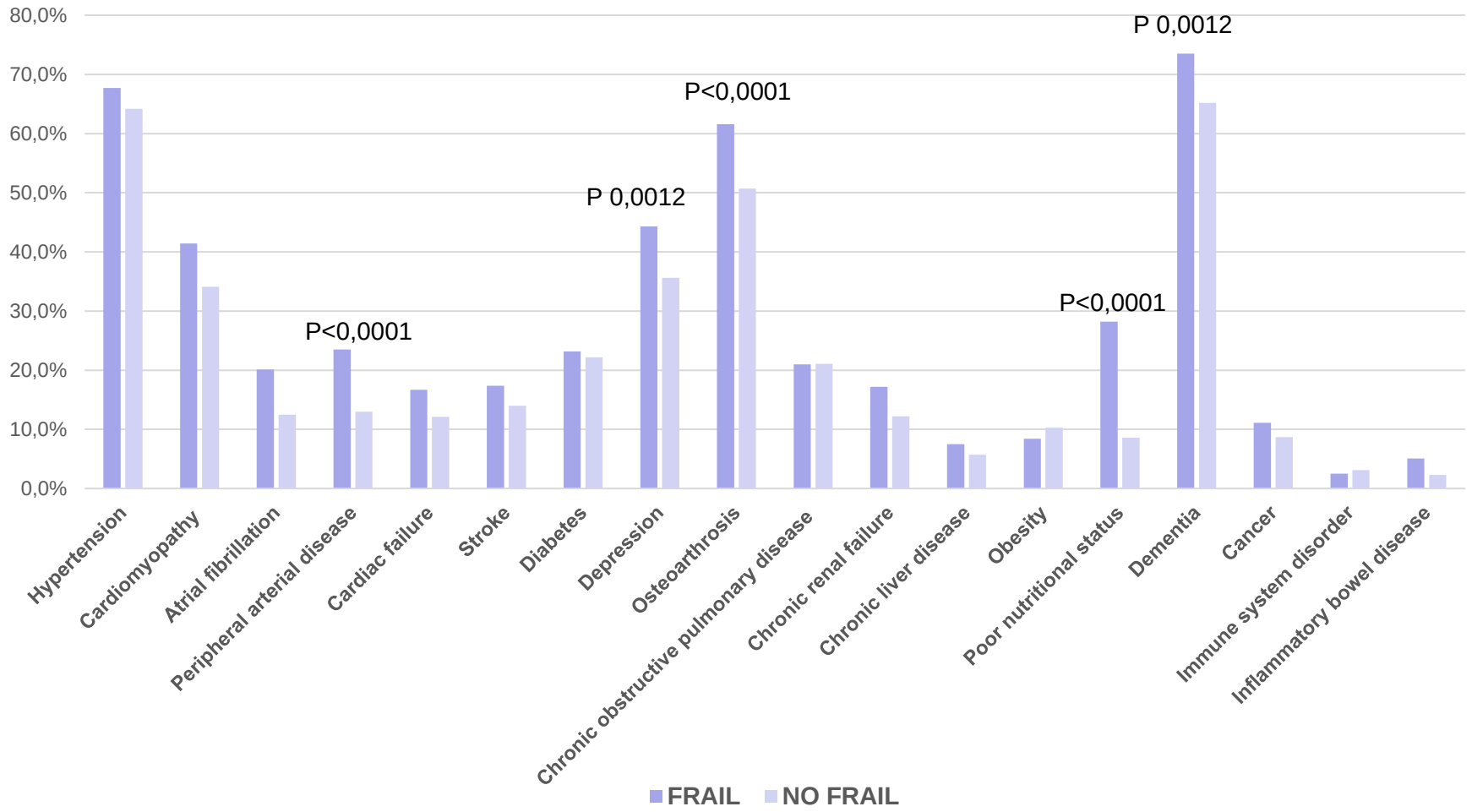
During the last months, had the patient performed less than 2-4 hours of light exercise per week? Yes No Unknown

GEROVAX STUDY

Il 25,9% dei residenti è risultato fragile secondo i criteri della FAC

	Frailty		
	Yes (n=467)	**No (n=1333)**	**p-value**
Sex, female, n (%)	348 (74.5)	907 (68.0)	0.0088
Age, years±SD	84.0±8.5	82.7±9.5	0.0005
Age classes, n (%)			<0.0001
60-79 years	105 (22.5)	466 (35.0)	
80-84 years	92 (19.7)	260 (19.5)	
85-89 years	135 (28.9)	271 (20.3)	
90+ years	135 (28.9)	336 (25.2)	

Frail


80,0%
70,0%
60,0%
50,0%
40,0%
30,0%
20,0%
10,0%
0,0%
P<0,0001
P 0,0012
P<0,0001
P<0,0001
P 0,0012
Hypertension
Cardiomyopathy
Atrial fibrillation
Peripheral arterial disease
Cardiac failure
Stroke
Diabetes
Depression
Osteoarthrosis
Chronic obstructive pulmonary disease
Chronic renal failure
Chronic liver disease
Obesity
Poor nutritional status
Dementia
Cancer
Immune system disorder
Inflammatory bowel disease
FRAIL
NO FRAIL

Frail

	FRAIL	NO FRAIL	
Number of comorbidities, n±SD	5.1±2.3	4.0±2.0	<0.0001
Number of drugs/day, n±SD	6.1±3.0	5.9±3.0	0.0257
Mobility, n (%)			
Independent/walk with aids	121 (26.1)	720 (54.3)	<0.0001
Moves with wheelchair	244 (52.7)	464 (35.0)	
Bedridden	98 (21.2)	141 (10.6)	

Outcome

Mortality

	Number of deaths	Death rate per 1000 person-years (95% CI)	p-value
Overall	508	172.06 (157.10, 187.10)	
Frail	90	211.73 (167.98, 255.47)	<0.001
Non-frail	369	127.59 (107.10, 148.07)	

Hospitalization

	Hospitalization n (%)	p-value
Overall	49 (4.0)	0.3062
Frail	10 (6.3)	
Non-frail	22 (4.3)	

Conclusioni Monitoraggio clinico

1. Il vaccino anti SARS CoV 2 è sicuro e causa eventi avversi di lieve entità
2. Le reazioni avverse a breve e lungo termine, associate al vaccino anti SARS CoV-2, sono state principalmente lievi o moderate
3. L'incidenza delle infezioni si riduce a seguito di vaccinazione e la severità di malattia è molto lieve, ma in alcuni casi COVID-19 può ancora causare decessi in residenti in RSA

Thanks!