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HCV: TREAT RATIO AND GOVERNANCE FOOTPRINTS.
ANALYSIS OF REGIONAL DIFFERENCES IN ITALY

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Introduction: The governance of Hepatitis C Virus (HCV) treatment in Italy is differentiated at regional level under a number of region factors: presence of technical document or guidelines, centralized or de-centralized purchasing, therapy access criteria, registers and number of prescription centres.

Due to such a fragmented model, a clear evidence of number of treated patients and related costs is hard to gather, and more in general it is difficult to compare how effective each regional system is with regard to access to treatment. A single KPI to harmonize the evaluation of cross-regional access to HCV treatment would allow a more objective assessment of the regional governance models.

Objectives: The present analysis aimed to compare the regional healthcare governance models in Italy with regard to HCV in order to assess regional differences in the access pathways to treatment. Specifically, the main goal of the study was to carry out a quantitative evaluation of the ability of a Region to give access to treatment for HCV diagnosed patients.
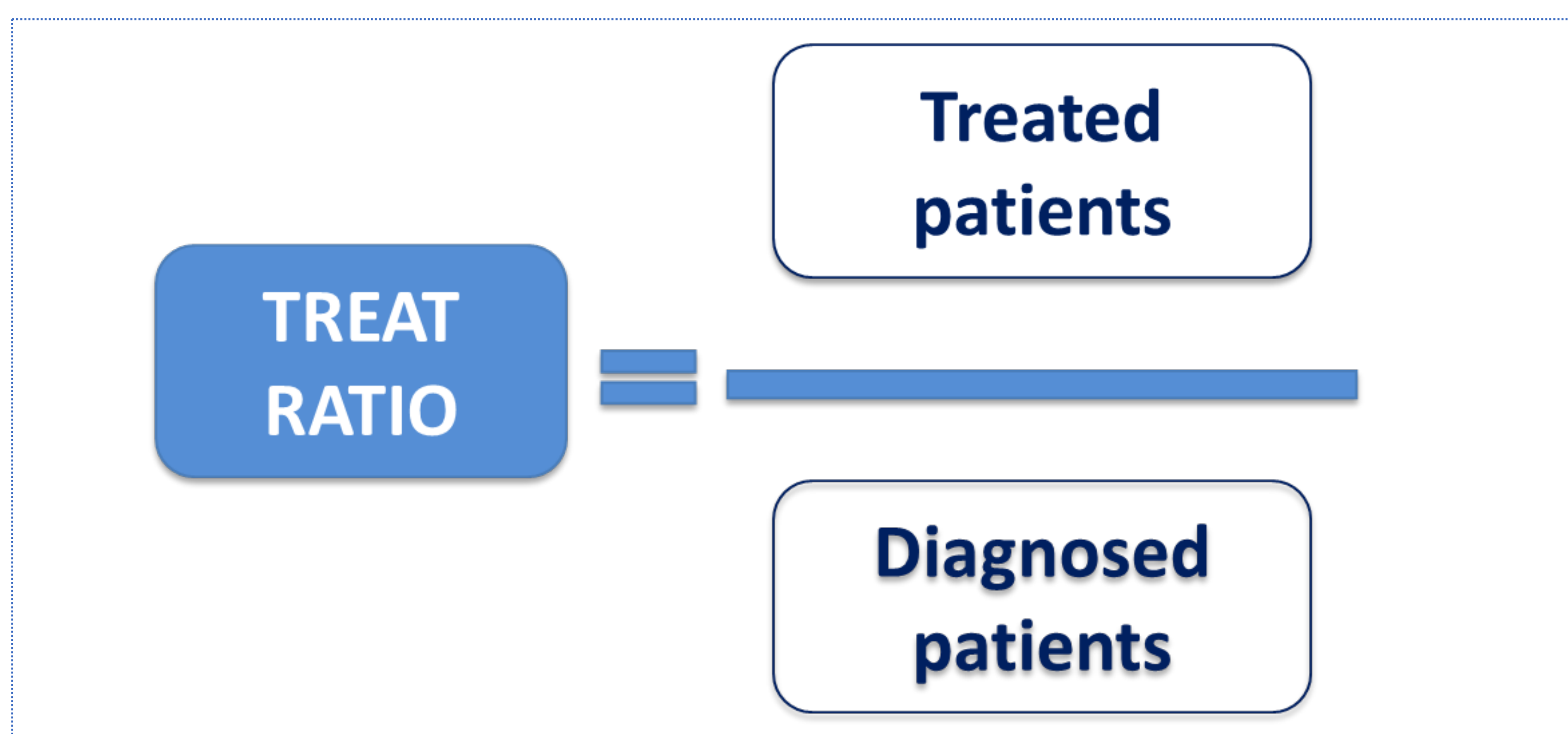

Figure 1. **Patient treated trend**
Source: Italian Medicines Agency (AIFA)

Methods: The analysis introduces a "treat ratio" (TR) to compare the ratio between patients who received HCV treatment and total number of diagnosed patients across all Regions. The regional prevalence of diagnosed patients was derived from a research by the patients association EpaC. The regional prevalence of patients receiving HCV treatment was estimated by distributing the overall number of treatments administered in Italy (derived from AIFA registries) proportionally to the regional prevalence of Sovaldi payback, assumed as proxy for the overall distribution of HCV treatments. TR allows to compare the regional governance footprints in light of multiple governmental aspects, such as clinical pathways, local regulatory bodies, buying centralization, prescription monitoring, prescribing centres coordination.

Figure 2. **Treat ration definition**
Source: Treated patients – Ma Provider assumption
Diagnosed patients - EPAC

Results: Sicily is the region with the highest TR value (73%), as a result of a wide treatment access combined with a limited diagnosed prevalence. Conversely, Campania results in a more selective access system, where despite of one of the highest diagnosis prevalence in Italy, only 1 HCV diagnosed patient out of four receives treatment (TR = 25%). Other big-spending regions such as Lombardy and Lazio are tied at a TR value of ~15%, while Veneto is among the most restrictive regions for HCV treatment access (TR = 12%). Friuli Venezia Giulia has the highest diagnosis prevalence (0,683%), but the lowest TR (5%) – this sounds as a further confirmation of how a TR-based comparison offers a more accurate evaluation. Sovaldi was the first entrant in all Regions, either tied or followed with a median 2 months' delay by Olysio.
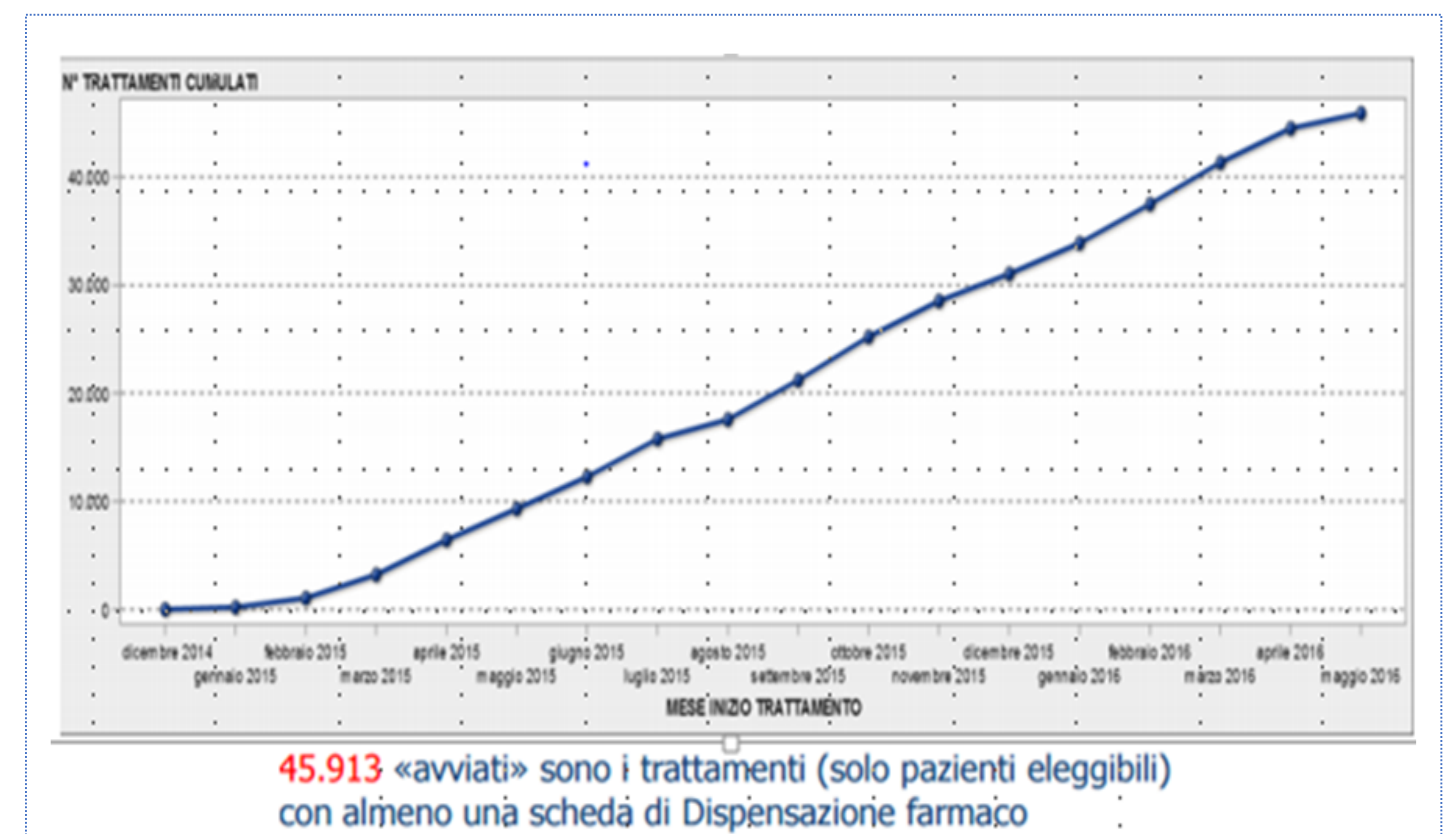
Regions	# Treated patients	Treated prevalence (A)	# exemptions for diagnosis	Prevalence of diagnosis (B)	Treat ratio (A/B)
SICILIA	3.966	0,078%	5.464	0,107%	73%
CALABRIA	1.855	0,094%	4.057	0,205%	46%
PUGLIA	6.392	0,156%	20.714	0,506%	31%
TOSCANA	4.245	0,113%	14.889	0,397%	29%
CAMPANIA	7.657	0,130%	30.448	0,519%	25%
ABRUZZO	480	0,036%	2.076	0,156%	23%
UMBRIA	418	0,047%	2.049	0,228%	20%
SARDEGNA	1.395	0,084%	6.898	0,415%	20%
LIGURIA	1.138	0,071%	6.338	0,398%	18%
MARCHE	625	0,040%	3.684	0,237%	17%
PIEMONTE	2.228	0,050%	14.084	0,317%	16%
LAZIO	2.570	0,044%	16.315	0,278%	16%
MOLISE	147	0,047%	979	0,311%	15%
LOMBARDIA	7.906	0,079%	54.430	0,546%	15%
BASILICATA	445	0,077%	3.401	0,588%	13%
V.D'AOSTA	51	0,039%	400	0,311%	13%
EMILIA	1.959	0,044%	16.292	0,366%	12%
VENETO	1.784	0,036%	15.104	0,307%	12%
BOLZANO	134	0,026%	1.259	0,244%	11%
TRENTO	112	0,021%	1.448	0,270%	8%
FRIULI	407	0,033%	8.394	0,683%	5%

Figure 3. **Treat Ratio in the Italian Regions**
Source: Ma Provider assumption

Conclusions: TR provides a robust KPI to compare access to treatment across Regions and serves as pivotal reference to investigate how local regulatory decisions and governance models impacts the access to treatment. As a general evidence, Regions where a technical document on HCV clinical pathways has been implemented by local regulatory bodies result in a higher number of treated patients.