CONFLICT OF INTEREST DISCLOSURE

Disclosure. Luca Degli Esposti reports no conflicts of interest in this work.

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Estimation of Metastatic Colorectal Cancer Patients Carrying BRAF Mutation Potentially Eligible to Targeted Therapy: a Real-World Evidence Study in Italy

Degli Esposti L[1], Sangiorgi L[1], Andretta M[2], Bacca M[3], Barbieri A[4], Bartolini F[5], Cavaliere A[6], Chinellato A[7], Ciaccia A[8], Cillo M[9], Citraro R[10], Costantini A[11], De Francesco A[10], Enieri N[7], Ferrante F[12], Gentile S[13], Lavalle A[13], Mancini D[3], Mensurati M[14], Moscogiuri R[15], Pastorello M[16], Procacci C[17], Re D[18], Santoleri F[11], Serao Creazzola S[19], Tegon M[7], Ubertazzo L[20], Vercellone A[21], Perrone V[1]

[1]CliCon S.r.l., Health, Economics & Outcomes Research, Bologna; [2]Azienda ULSS 8 Berica, Vicenza; [3]ASL Brindisi, Brindisi; [4]ASL Vercelli, Vercelli; [5]USL UMBRIA 2, Terni; [6]ASL Viterbo, Viterbo; [7]Azienda ULSS 3 Serenissima, Mestre (VE); [8]ASL Foggia, Foggia; [9]ASL Salerno, Salerno; [10]Dipartimento di Scienze della Salute, Università Magna Grecia di Catanzaro, Catanzaro; [11]ASL Pescara, Pescara; [12]ASL Frosinone, Frosinone; [13]Direzione Generale per la Salute Regione Molise, Campobasso; [14]ASL Roma 3, Roma; [15]ASL Taranto, Taranto; [16]ASP Palermo, Palermo; [17]ASL BAT, Andria (BT); [18]ASL Teramo, Teramo; [19]ASL Napoli 1, Napoli; [20]ASL Roma 4, Civitavecchia (RM); [21]ASL Napoli 3 SUD, Torre del Greco (NA)

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BACKGROUND AND OBJECTIVES

- The development of **innovative targeted therapies** in oncology has significantly improved the survival and quality of life of cancer patients [1].
- In a limited-resource system such as that of the National Health Service, the introduction of targeted therapy, characterized by high costs, made it necessary **to balance the innovation** with **prescriptive appropriateness** and **economic sustainability** [2].
- In this context, **the identification of patients eligible to targeted therapies** represents a key factor for ensuring such balance.
- **The aim of the present study was to evaluate the possibility of identifying metastatic colorectal cancer (mCRC) patients carrying BRAF gene mutation, potentially eligible to targeted therapy, by linking administrative and pathological anatomy databases.**

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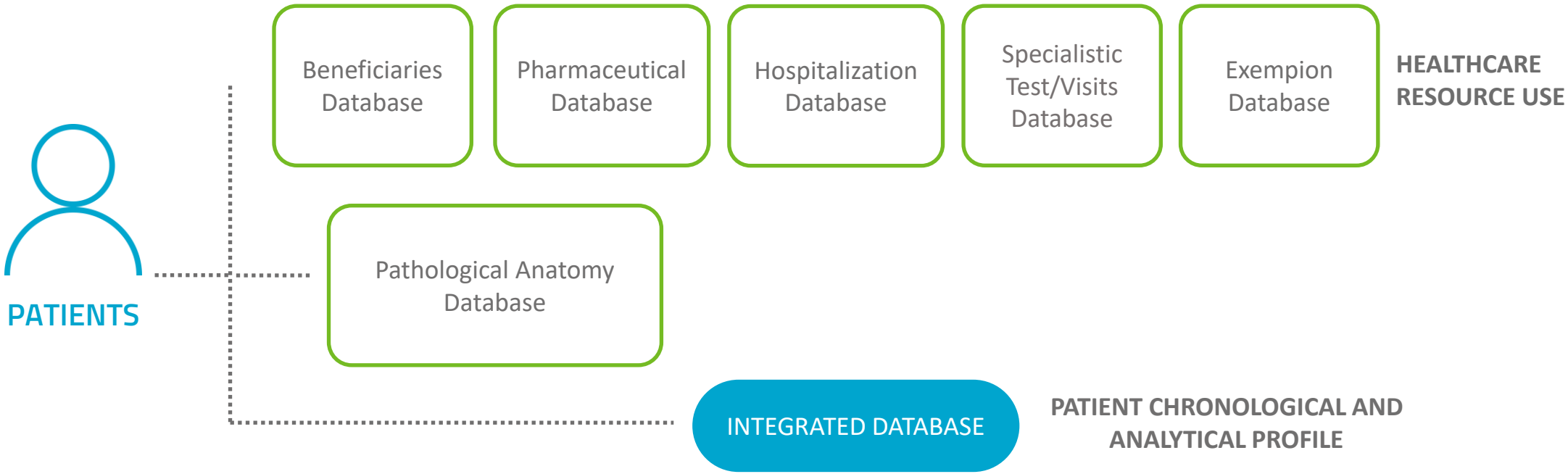
References:
[1] Falzone L, et al. Front Pharmacol. 2018;9:1300
[2] Conti RM, N Engl J Med. 2016;374:703-6

METHODS
DATA SOURCE

A ***retrospective study*** was conducted across **2013-2019** in a sample of Italian Entities, using the data-linkage between administrative and pathological anatomy (PA) databases.



"The integration of administrative datasets makes it possible to represent the patient's entire clinical history and not just individual prescriptions. The analyzes were conducted on exclusively anonymous data in full compliance with privacy regulations. Clicon s.r.l. has obtained the approval as per legislation by all the Ethics Committees to analyze these data. The results are exclusively in aggregated form and never attributable to a single institution, department, doctor, individual, or individual prescribing behaviors. The study was conducted in full compliance with current legislation for retrospective studies."

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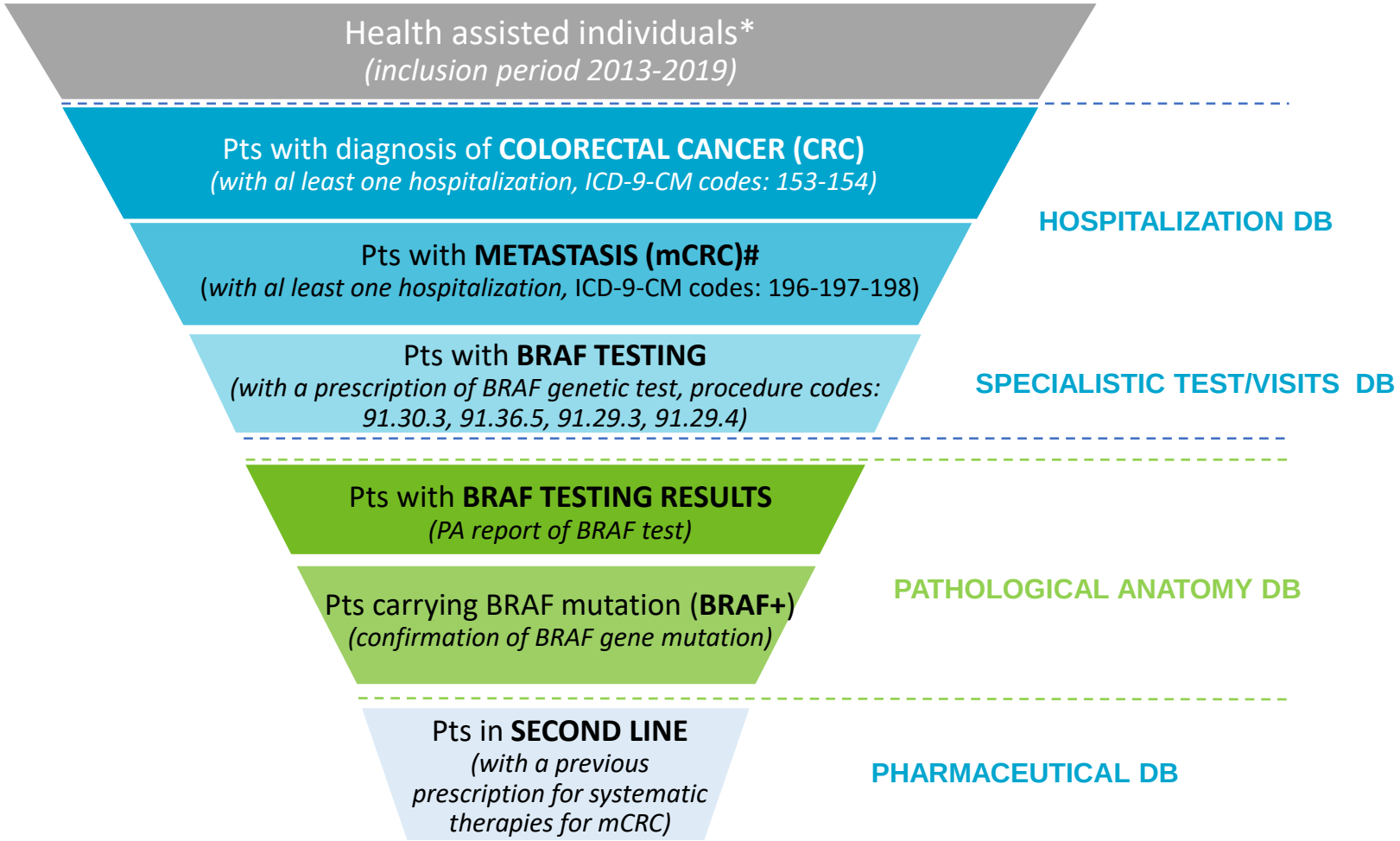
METHODS
FLOWCHART OF STUDY POPULATION SELECTION



Patients potentially eligible for targeted therapy

** Data were reported per million of health-assisted individuals*
 # The metastasis diagnosis was evaluated both at CRC diagnosis and during the follow-up

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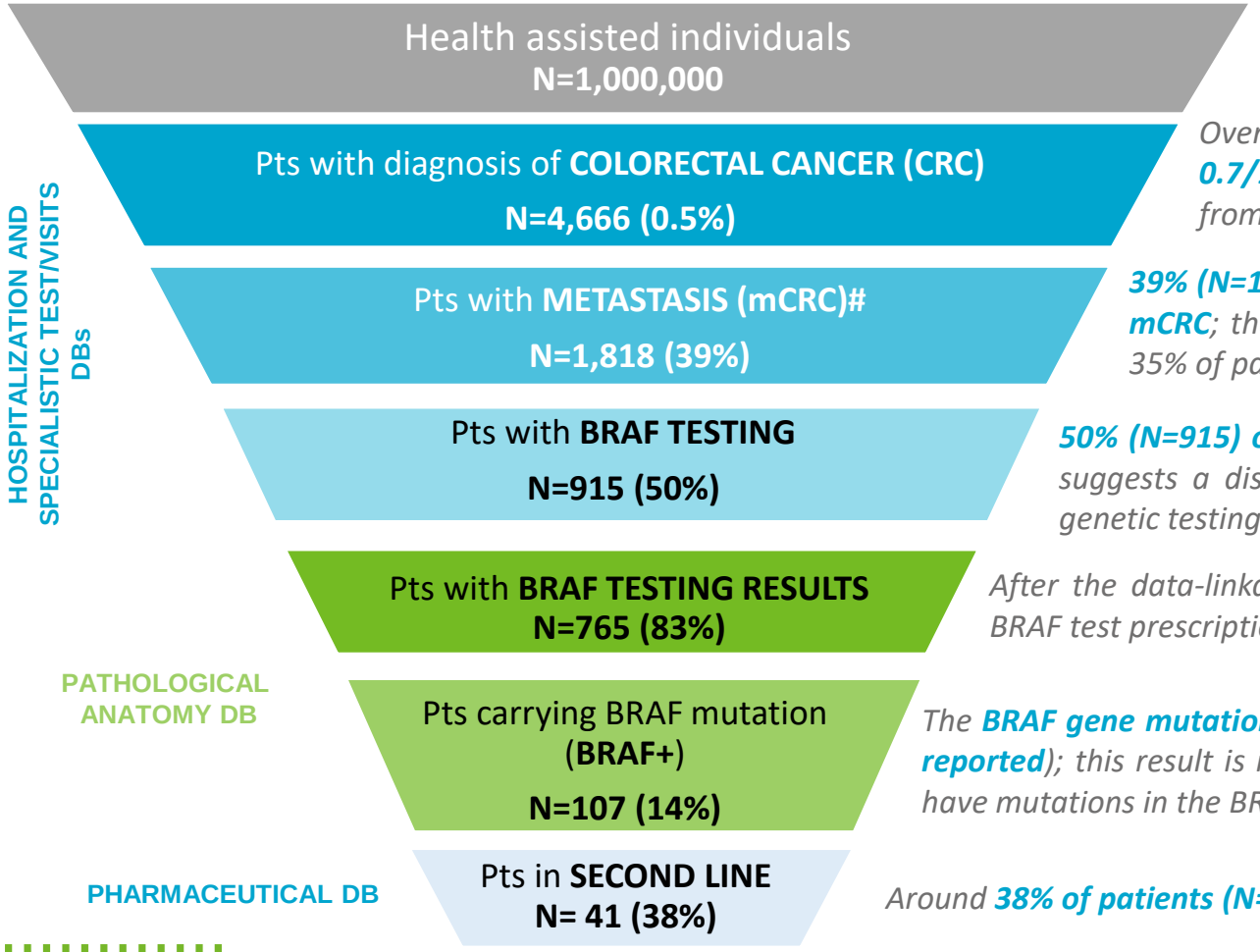
RESULTS
ESTIMATION OF PATIENTS WITH mCRC CARRYING BRAF MUTATION POTENTIALLY ELIGIBLE FOR THE "*TARGETED THERAPY*"



*Overall, **4,666 CRC patients** were identified, with an incidence (2019) **estimated of 0.7/1,000** of health-assisted individuals [in line with epidemiological available data from AIRTUM* (**0.8/1,000 of health-assisted individuals, in 2019**)][1].*

***39% (N=1,818) of patients** had at least **one metastasis;** therefore, they were **identified as mCRC**; these results were consistent with those available in the literature (i.e., about 20-35% of patients with CRC present metastases at diagnosis) [2,3].*

***50% (N=915) of mCRC patients** had an **outpatient prescription for the BRAF test**. These data suggests a discrepancy between the clinical practice and guidelines, which recommend the genetic testing in all patients with mCRC [4].*

*After the data-linkage between administrative and PA databases, **83% (N=765)** of patients with BRAF test prescription **performed the test** (with a PA report available).*

*The **BRAF gene mutation was confirmed in 107 patients** (equal to **14% of patients with the BRAF test reported**); this result is in line with the published work (i.e., approximately 10% of patients with mCRC have mutations in the BRAF gene) [4].*

*Around **38% of patients (N=40**) were estimated with a **previous systemic line** for mCRC.*

Patients with mCRC BRAF+ and potentially eligible for "targeted therapy"

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References:
[1] https://www.registri-tumori.it
[2] Zacharakis M, et al., Anticancer Res. 2010;30(2):653-60.
[3] Rumpold H, et al., BMC Cancer. 2020;20(1):1149.
[4] https://www.aiom.it
*AIRTUM, Associazione Italiana Registri Tumori:

CONCLUSIONS
TAKE-HOME MESSAGE

1 The analysis of ***real-world data*** allowed to estimate the quote of patients ***potentially eligible for targeted therapy*** in the clinical practice setting.

2 The epidemiologic scenario reported in our analysis showed an ***annual incidence of CRC*** in Italy of ***0.7/1,000 health-assisted individuals*** and around 40% of ***metastatic patients***, consistently with published available literature, suggesting that ***our methodology could be a supportive*** tool to identify ***eligible patients for targeted therapy.***

3 Furthermore, the use of the pathological anatomy flow would allow to ***identify and quantify patients with a specific genetic profile*** required to access to innovative therapies, thus enabling to ***estimate health-costs*** and to ***plan the pharmaceutical expenditure*** in a perspective of economic sustainability.

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**CliCon S.r.l., Health, Economics & Outcomes Research, Bologna, Italy*

Contact Information:
Luca Degli Esposti
luca.degliesposti@clicon.it

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