GenoMed4All & ERN-EuroBloodNet

Educational Program on AI in Hematology for an expert audience

#6

Use case: Multiple Myeloma
Overview of results (both from a technical and clinical perspective) + specific onboarding requirements (e.g. minimal dataset)

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SUMMARY

- ❑ Multiple Myeloma: clinical and biological context
- ❑ Current risk definition and the last update: Barcelona criteria
- ❑ Examples of AI implementation in Multiple Myeloma

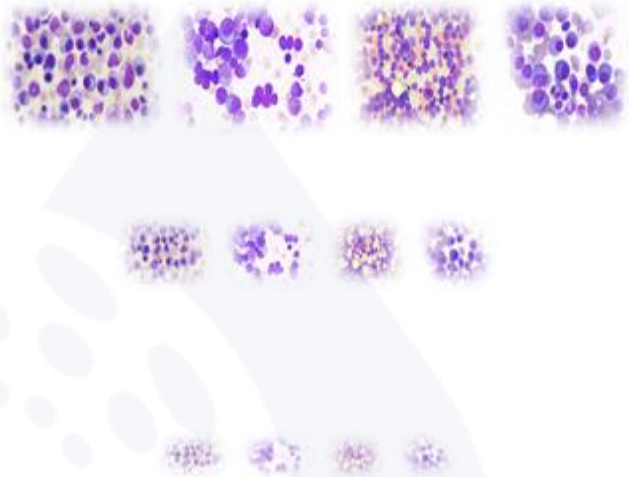
- ❑ GENOMED4ALL: Multiple Myeloma use case and specific aims
- ❑ DATASET description: BOLOGNA dataset + CoMMpass dataset

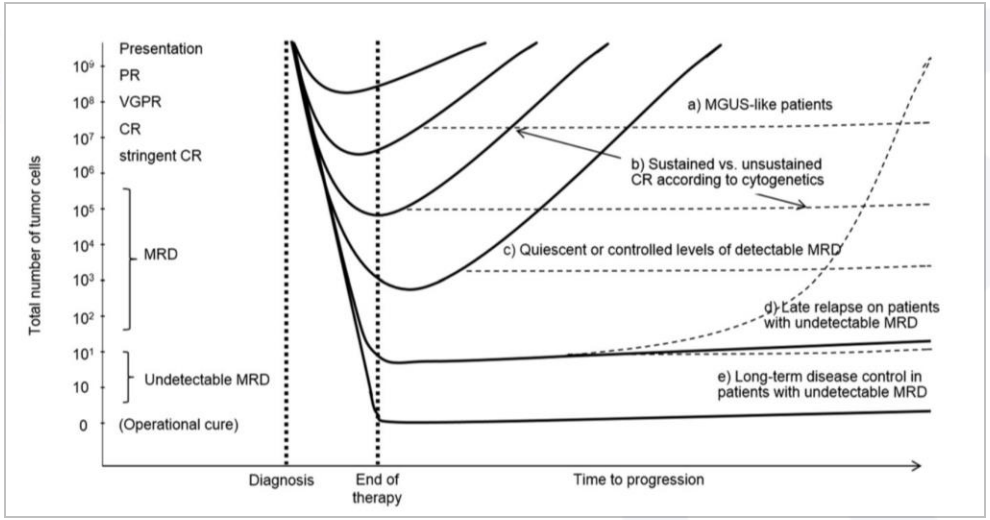
- ❑ Overview of results

1. FEDERATED LEARNING – Universidad Politécnica de Madrid
2. DATA MODELLING - ML TRAINING ALGORYTHMS FOR RISK PREDICTION – University of Turin
3. RADIOMICS – University of Bologna

INTRODUCTION
Multiple Myeloma(s)

Absence of a unique marker → persistence of tumor cells → MRD relevance





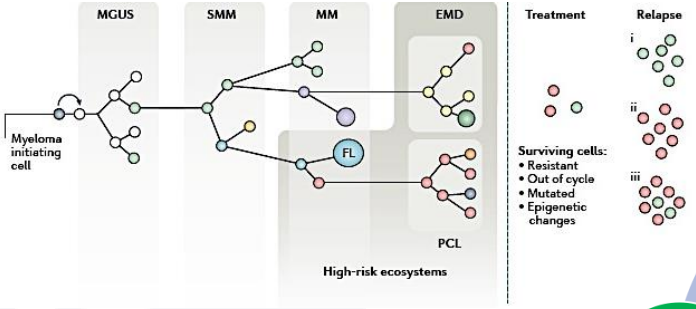
Need to understand the biology of MM and MRD clones so they can be targeted to achieve a cure considering short and long-term side effects

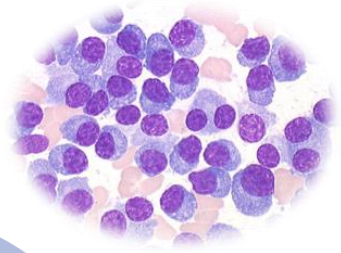
Morgan GJ et al., Nat Rev Cancer 2012
Kumar SK et al., Nat Rev Clin Oncology 2018

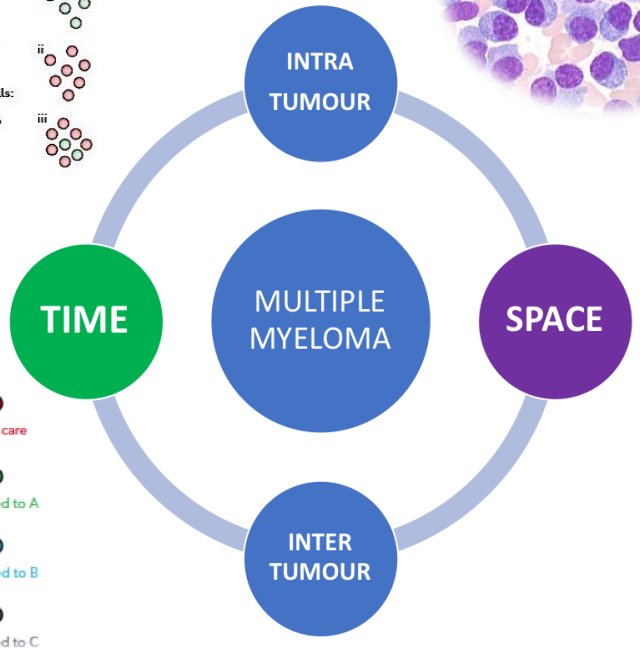
Munshi N, et al. *JAMA Oncology*. 2016
Munshi N et al., JAMA Onc 2017
Pawlyn C et al., Blood 2019

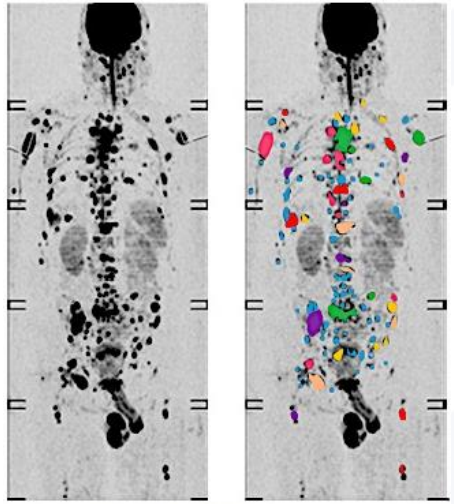
Landgren O et al., Seminar Hemat 2018
Paiva B et al., Blood 2020

MM Four layers of heterogeneity









Current Multiple Myeloma risk stratification scores

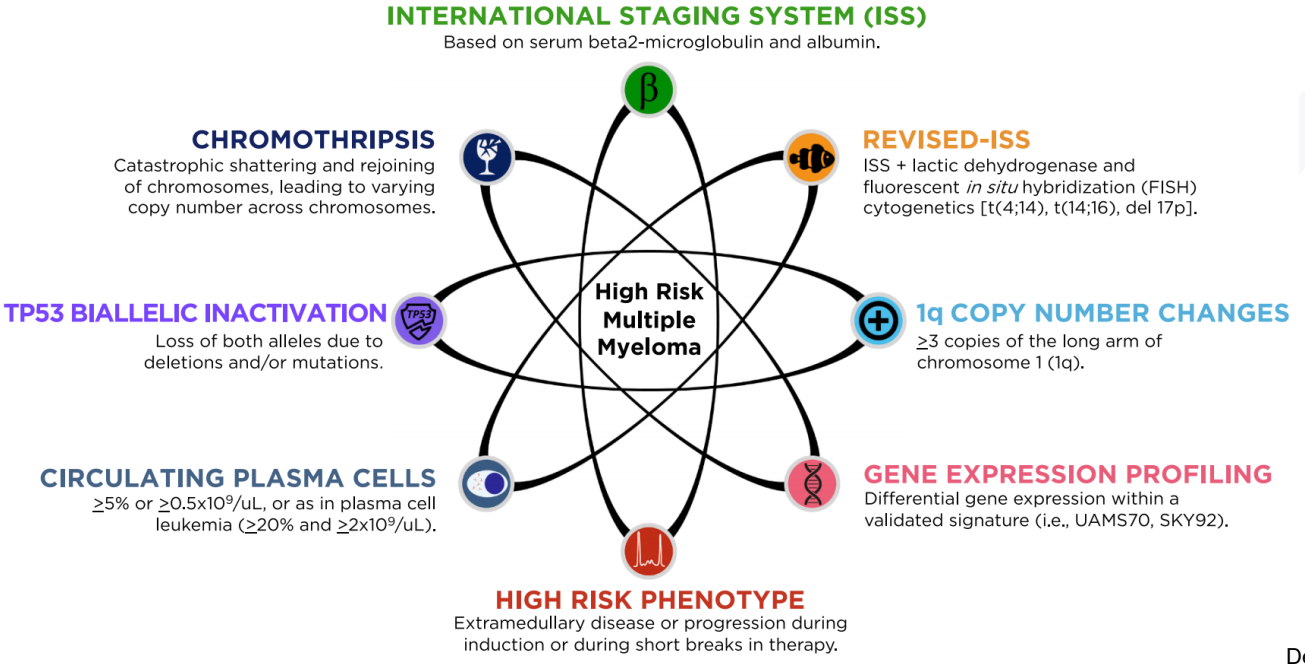
	ISS	IMWG	R-ISS	R2-ISS	Cytogenetics Prognostic Index
Serum features	β2-microglobulin Albumin	β2-microglobulin Albumin	LDH β2-microglobulin Albumin	LDH β2-microglobulin Albumin	none
Genomic features	none	del(17p) t(4;14) +1q21	del(17p) t(4;14) t(14;16)	del(17p) t(4;14) +1q21	del(17p) t(4;14) del(1p32) 1q21 gain trisomies 3, 5, 21
% HR	**33.6%**	**20%**	**10%**	**8.8%**	**11-18%**
Definition of HR	ISS III: β2-microglobulin ≥5.5 mg/L	ISS II/III and t(4;14) or 17p13 del by iFISH	ISS III and either high-risk CA by iFISH or high LDH	3-5 points	Prognostic index >1 defined high risk
Outcomes based on risk	Median OS Stage I: 62 Stage II: 45 Stage III:29	Median OS Low Risk: >120 Standard risk: 84 High risk: 24	Median OS Stage I: 66 Stage II: 42 Stage III: 37	Median OS I: nr II: 109.2 III: 68.5 IV: 37.9	5-years OS High-risk: <50% Int risk: 50-75% Low risk: >75%

Greipp P et al., JCO 2005 Chng WJ et al., Leukemia 2014 Palumbo A et al., JCO 2015 D'Agostino M et al., JCO 2022 Perrot A et al., JCO 2019

MULTIPLE MYELOMA

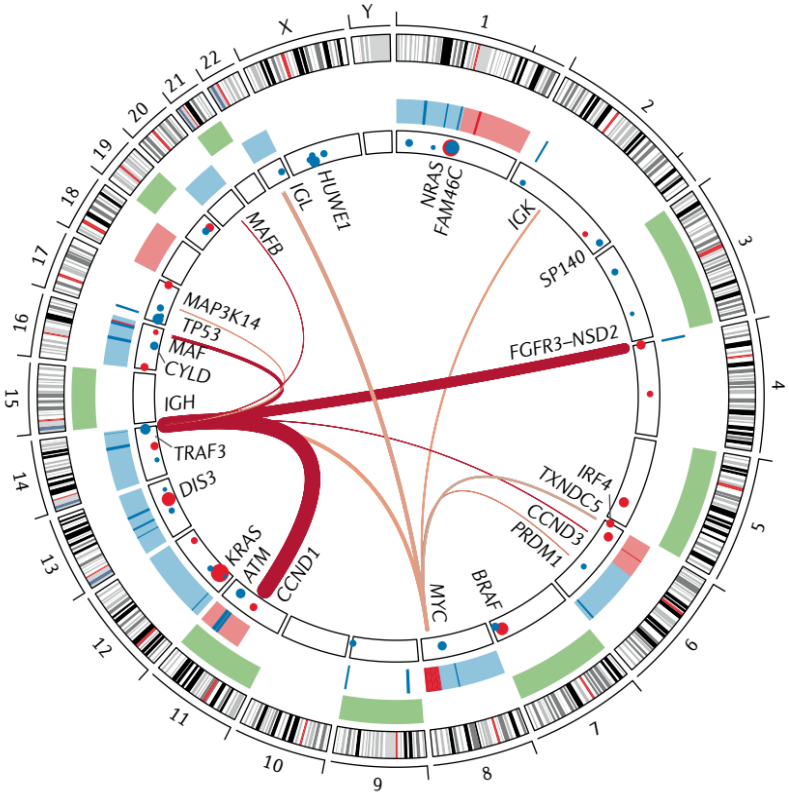
Definition of High risk patients

Disease risk is best measured on a spectrum rather than as a dichotomous entity



Derman B et al., Blood Reviews 2022

More wide genomic panorama: how to manage it?



CNVs

- Hyperdiploidy
- Large gain
- Focal gain
- Large loss
- Focal loss

Somatic (tumour) variants

- SNV in oncogenes
- SNV in tumour suppressor genes
- 1%
- 3%
- 20%

Translocations

- 1%
- 16%

Structural variant frequency (% of patients)

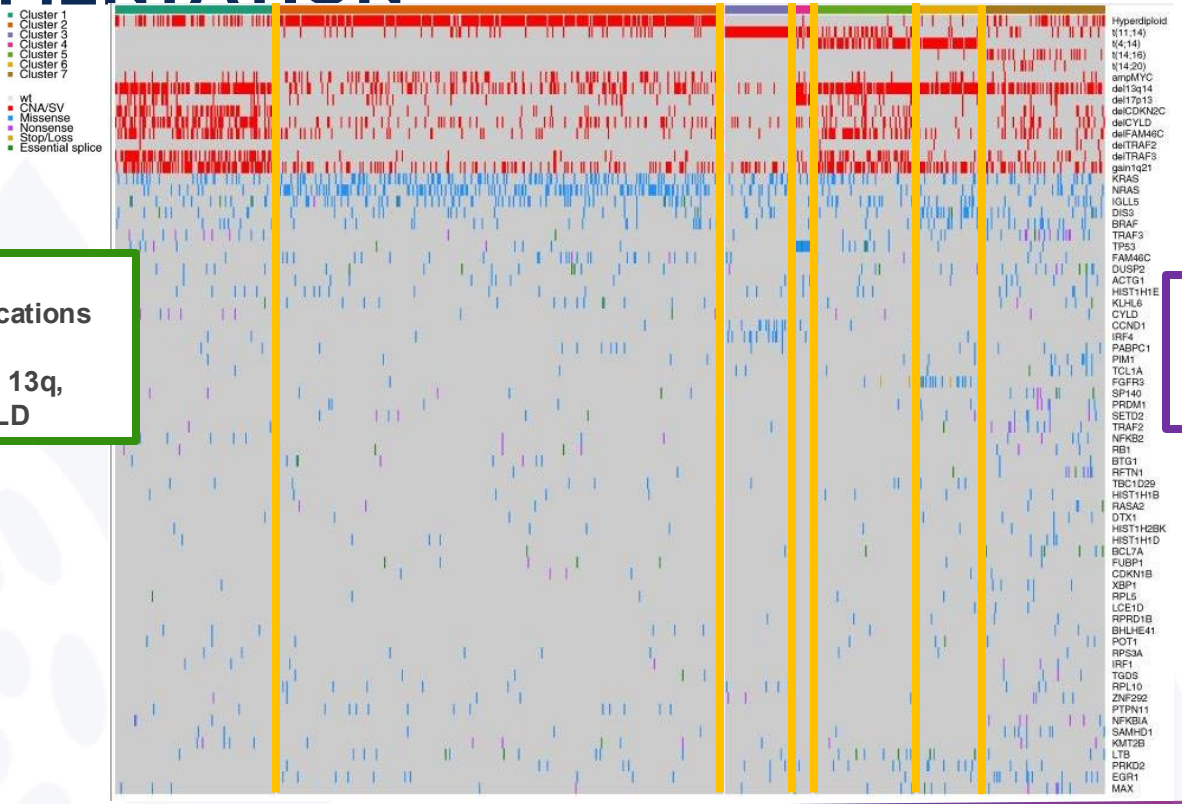
- ≥50%
- 25%

Median allelic frequency (% of patients)

- **Inconsistencies between risk definitions**
- **Different methods**
- **Cut-off issues**

Dutta AK et al., Nat Rev 2022

CO-OCCURRENCE and PATIENTS' SEGMENTATION



CLUSTER1
No IGH translocations
Amp1q
Del 1p13, 1p32, 13q, TRAF3 and CYLD

CLUSTER7
No Hyperdiploidy
t(11;14)
Driver mutations

Maura F et al., Nat Comm 2019

IMS consensus on genomic definition of high risk myeloma

Del17p
in more than 20% of plasma cells

TP53 mut
(no threshold VAF)

Del(1p32)$^{del/del}$

t(4;14) or **t(14;16)** or **t(14;20)**
+
Gain/amp 1q or **del(1p32)$^{del/wt}$**

Gain/amp 1q
+
del(1p32)$^{del/wt}$

Manuscript in preparation

MULTIPLE MYELOMA RISK ASSESSMENT IN 2024
SOME limits → POSSIBLE solutions

1. MYELOMA BIOLOGY IS COMPLEX…and MIGHT CHANGE OVER TIME

- How to better discriminate patients into different risk categories?
- How to better integrate static with dynamic model of risk assessment?

MULTIFACTORS INTEGRATION

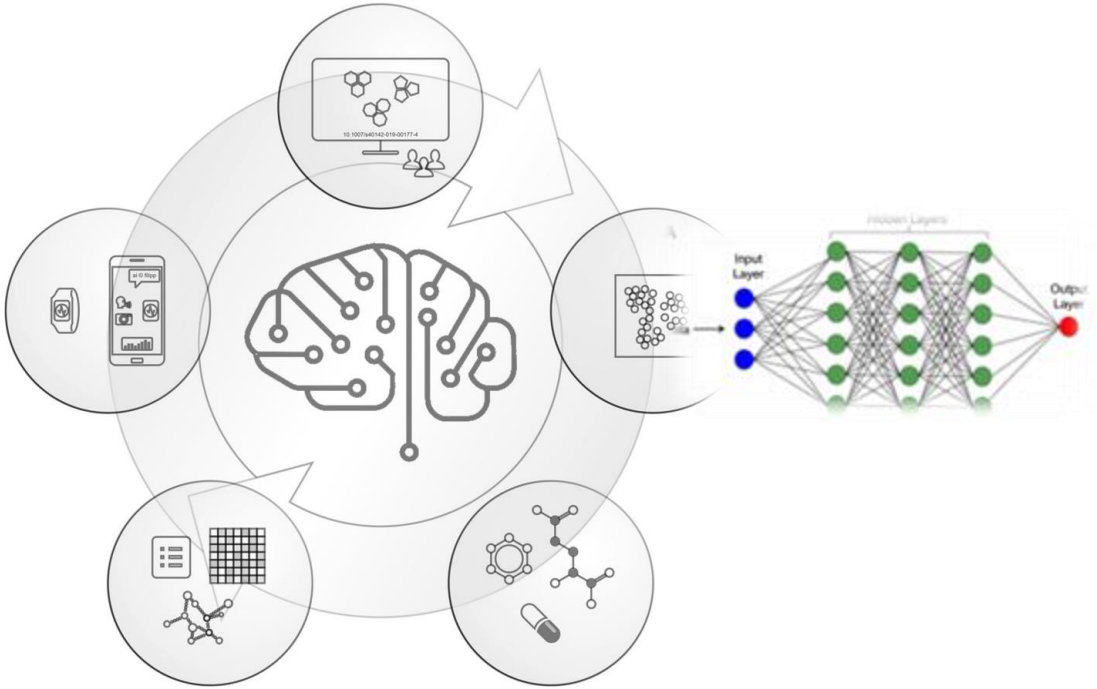
TIMING

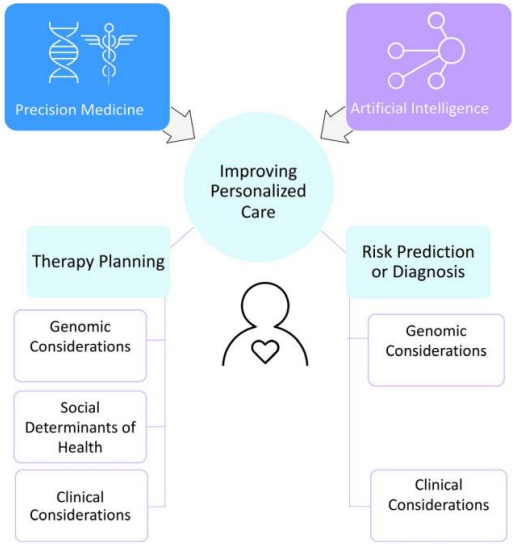
TUMOR SIZE

2. MRD is THE BEST MM PROGNOSTICATOR, BUT OUTCOMES ARE HETEROGENEOUS

- How to improve MRD evaluation?
- How to integrate BM with imaging/peripheral blood techniques?

SOLUTION TO IMPROVE MULTIFACTORS INTEGRATION
Artificial Intelligence and deep learning systems





To develop decisional algorithms to be used to improve patients' management

SOLUTIONS TO IMPROVE MULTIFACTORS INTEGRATION
Artificial Intelligence and deep learning systems

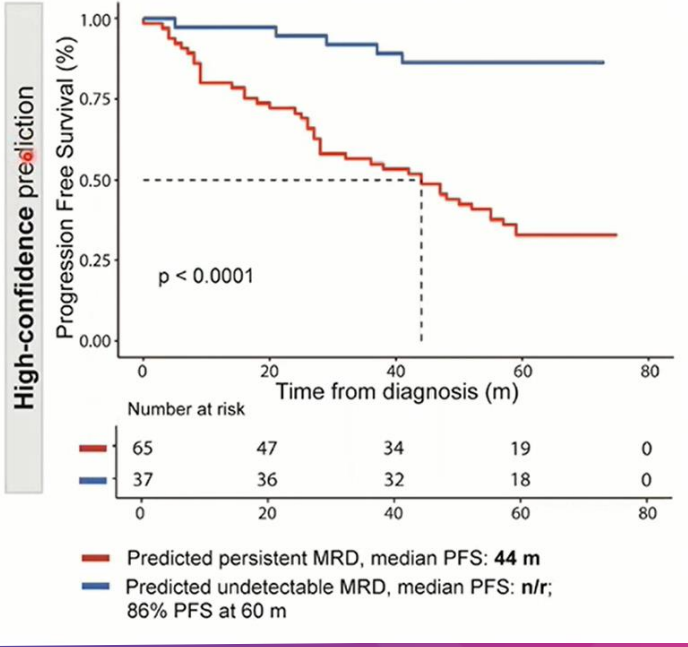
Tumor and immune biomarkers to predict undetectable MRD

A machine learning model developed in transplant-eligible MM

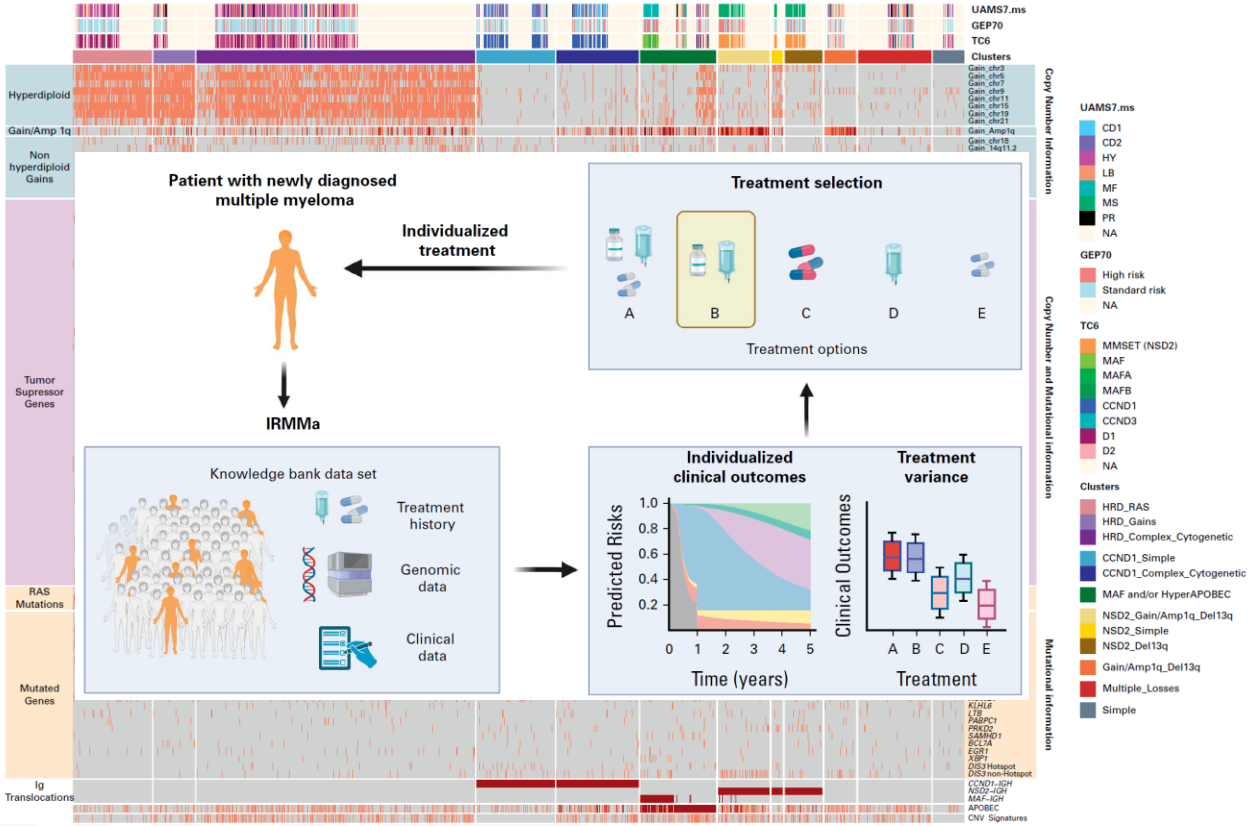
Variable	Sustained und. MRD (n/N)	Non-sustained und. MRD (n/N)	Log odds [CI]	P
ISS Stage I *(vs II and III)*	36/90	62/164	0.10 [-0.4; 0.6]	0.73
ISS Stage III *(vs I and II)*	15/90	41/164	-0.51 [-1.2; 0.1]	0.13
R-ISS Stage I *(vs II and III)*	26/73	42/142	0.28 [-0.3; 0.9]	0.37
R-ISS Stage III (vs I and II)	5/73	16/142	-0.54 [-1.6; 0.5]	0.30
Elevated LDH levels	8/87	28/156	-0.78 [-1.6; 0.1]	0.07
gain(1q)	28/71	62/139	-0.21 [-0.8; 0.4]	0.48
t(4;14)	9/76	27/150	-0.49 [-1.3; 0.3]	0.23
t(14;16)	4/58	7/118	0.16 [-1.1; 1.4]	0.80
del(17p13)	4/76	21/150	-1.08[-2.2; 0.0]	0.05
del(17p13) and/or t(4;14)	13/90	41/164	-0.67 [-1.3; 0.0]	0.05
CTCs (>0.735)	39/90	102/164	-0.78 [-1.3; -0.2]	**0.004**
PC clonality (>13.39)	12/90	56/164	-1.20 [-1.9; -0.5]	**<0.001**
Myeloid precursors (>0.21)	45/90	62/164	0.50 [0.0; 1.0]	0.06
NK $CD56_{bright}$ $CD27_{neg}$ cells (>0.04)	32/90	84/164	-0.63 [-1.2; -0.1]	**0.02**
Eosinophils (>1.76)	55/90	74/164	0.65 [0.1; 1.2]	**0.02**
$CD27_{neg}$ $CD38_{pos}$ T cells (>0.61)	12/90	39/164	-0.71 [-1.4; 0.0]	0.05
Mature B cells (>1.75)	20/90	35/164	0.05 [-0.6; 0.7]	0.90
Intermediate neutrophils (>36.33)	9/90	15/164	0.10 [-0.8; 1.0]	0.80
Predicted und. MRD *(standard confidence)*	62/90	57/164	1.44 [0.9; 2.0]	**<0.001**
Predicted und. MRD *(high confidence)*	25/37	15/84	2.26 [1.4; 3.1]	**<0.001**

Increased odds of sustained undetectable MRD

-2 -1 0 1 2 3



Genomic Classification and Individualized Prognosis in Multiple Myeloma



IRMMa → for estimating individualized risk and treatment variance of NDMM as an online tool for the research community

Maura F et al, JCO 2024

GenoMed4All: Multiple Myeloma Use Case

Aim of the study

- **Research question:** can we identify **predictors** of early relapse (i.e. within 12-18 months from the start of therapy), based on the **INTEGRATION of baseline genomic, clinical & imaging data**?

GenoMed4All: Multiple Myeloma Use Case

Dataset

SERVIZIO SANITARIO REGIONALE
EMILIA-ROMAGNA
Azienda Ospedaliero - Universitaria di Bologna
IRCCS Istituto di Ricovero e Cura a Carattere Scientifico

POLICLINICO DI
SANT'ORSOLA

MM RF MULTIPLE MYELOMA Research Foundation

db GaP
GENOTYPES and PHENOTYPES

Bologna Dataset

PI-based triplet therapy
253 NDMM patients
Genomic (79 features: SNP array, ULP-WGS)
Clinical (60 features: Biochemical,Response, Survival)
Imaging (PET/CT scans, and annotated data)

CoMMpass Dataset

PI- based triplet therapy
1144 NDMM patients
826 with Genomic (79 features: WGS/WES)
Clinical (29 features: Biochemical, Response, Survival)
Raw data downloaded from dbGap (dbGaP Study Accession: phs000748.v7.p4) and from MMRF partner portal (https://research.themmrf.org)

ebn ERN | EuroBloodNet
GENOMED 4ALL

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Dataset harmonization

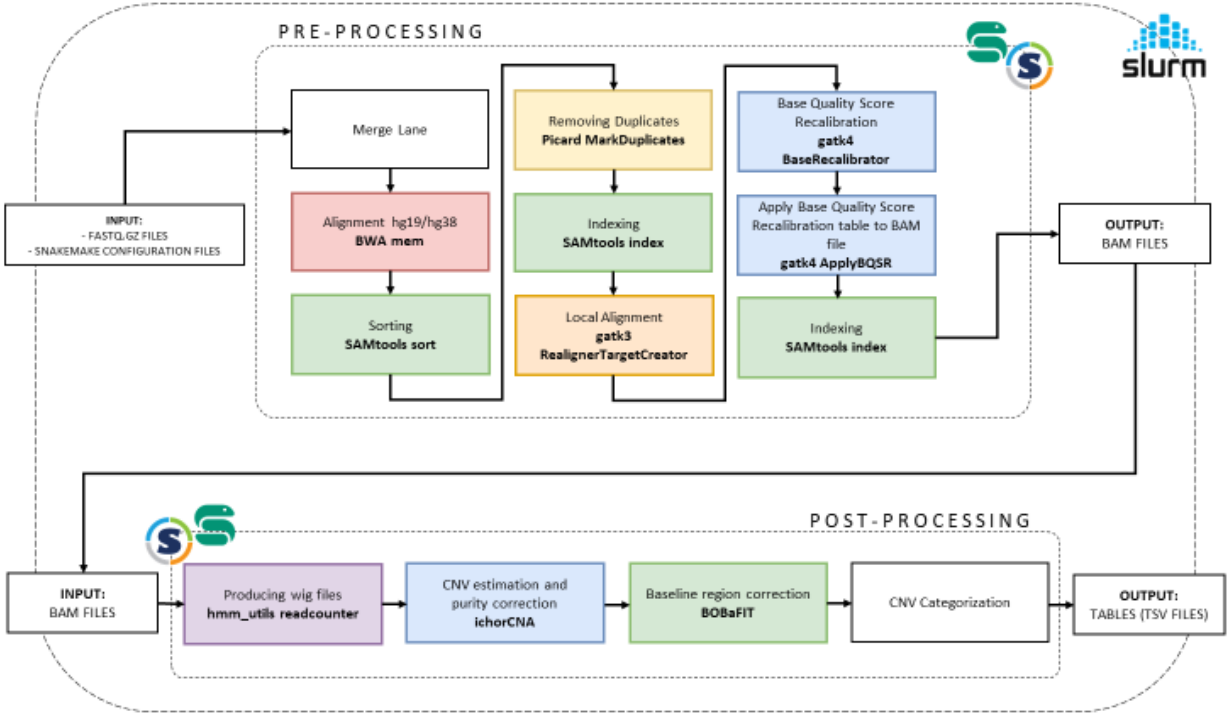
Column name	Description
Id	Patient code
Method	DNA Profilation method. 1 = SNParray, 2 = ULP-WGS
amp	Binary classification output for amplification at arm-level (1/0)
del	Binary classification output for deletion at arm-level (1/0)

Clinical data variables were harmonized to the MM Bologna clinical variables in terms of unit of measure and variable names. Notably, translocations data variables could not be perfectly harmonized due to a difference in the technology used to generate the information (FISH for MM Bologna database and WGS for COMMPASS database). This issue was addressed by utilizing Seq-FISH data provided by the MMRF partner portal, which emulates traditional FISH results using WGS data.

- **The set of clinical variables provided for CoMMpass dataset is thus identical to the ones included in the MM Bologna clinical dataset**

GenoMed4All: Multiple Myeloma Use Case

Pipeline for genomic data processing



GenoMed4All: Multiple Myeloma Use Case

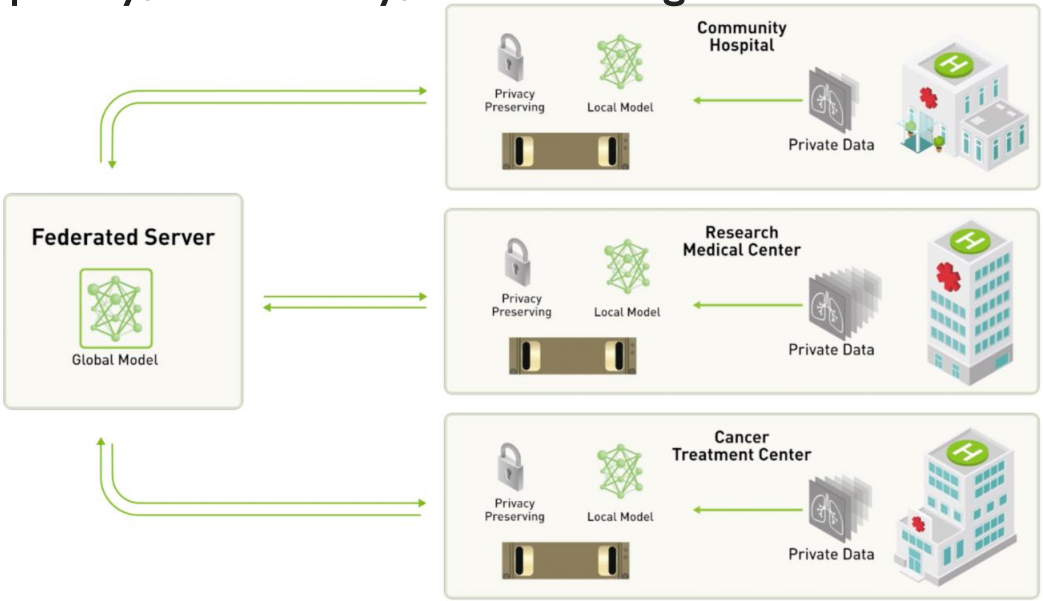
Ongoing analyses

1. FEDERATED LEARNING – UPM
2. DATA MODELLING and ML TRAINING ALGORYTHMS FOR RISK PREDICTION – UNIBO -UNITO
3. RADIOMICS - UNIBO

GenoMed4All: Multiple Myeloma Use Case

Federated Learning (also known as *collaborative learning*)

DEF: machine learning technique that trains an algorithm via multiple independent sessions, each using its own dataset without sharing data thus addressing critical issues such as data privacy, data security, data access rights and access to heterogeneous data



DATASET DISCUSSION
FEATURES SELECTION

SYNTHETIC DATA GENERATION

SYNTHETIC DATA VALIDATION

GenoMed4All: Multiple Myeloma Use Case

AIM: to demonstrate the benefits of implementing federated learning

- Data preprocessing (dataset discussion, features selection)
- Cleaning data
- To obtain a final .csv with 1388 patients and 12 features for generation

MPC	OLD_0_1	SEX	CREATININE	HB	HB_m_105	PLT	PLT_m_150	PC_TOT	PC_M_60	IG_ISOTYPE	LIGHT_CHAIN	CALCIUM	Calcio_M_105	PFS_I_EVENT	PFS_I_MONTHS	Early Relapse
MPC_424	0	M	6.66	4.9	1	141	1	100	1	BJ	lambda	8.5	0	1	10	1
MPC_269	0	M	7										0	1	21	0
MPC_538	0	M	0.85	10.8	0	525	0			BJ	kappa	16.1	1	1	0	1
MPC_427	0	F	0.52	11.3	0	294	0	80	1	BJ	lambda	9.2	0	0	26	0
MPC_375	0	M	0.86	13	0	275	0	80	1	BJ	lambda	10.6	1	0	55	0
MPC_483	0	F	0.71	10.7	0	227	0	20	0	IgG	kappa	9.1	0	1	3	1
MPC_429	1	F	0.73	11.7	0	275	0	80	1	IgG	Kappa	9.1	0	1	26	0
MPC_430	1	M	0.69	10.5	1	116	1			IgG	kappa	10.9	1	1	26	0
MPC_330	0	F	0.73	8.9	1	299	0	80	1	IgG	kappa	8.8	0	0	43	0
MPC_401	0	M	1	13.2	0	292	0	40	0	IgG	kappa	10.4	0	0	50	0
MPC_519	0	M	1.43	9.1	1	177	0	90	1	ns	Lambda	10	0	1	24	0
MPC_402	1	M	1.53	10.3	1	283	0	70	1	IgG	kappa	9.5	0	0	37	0
MPC_337	0	M	0.72	12.6	0	249	0	20	0	IgG	kappa	9.6	0	0	44	0
MPC_270	1	M	1.34	12	0	233	0			IgG		9.8	0	1	9	1
MPC_403	0	M	1.02	12.3	0	275	0	80	1	IgG	kappa	10.5	1	0	43	0
MPC_474	0	F	0.85	11.3	0	255	0	30	0	IgG	kappa	9.6	0	0	41	0
MPC_1771		M	8	10.6	0	85	0	10	0	BJ	kappa	8.2	0	1	13	0
MPC_480	0	F	0.64	12	0	174	0	10	0	NS	Kappa	9.3	0	1	37	0
MPC_488	1	F	1.79	11.4	0	66	1	10	0	IgG	kappa	9.4	0	1	30	0
MPC_857	1	M	0.9	15.2	0	253	0	5	0	IgG	lambda	9.6	0	0	38	0
MPC_409	0	M	0.88	15.2	0	270	0	50	0		lambda	10.7	1	1	21	0
MPC_305	0	M	2.5	8.7	1	94	1	50	0	IgG	Kappa	11	1	1	10	1

GenoMed4All: Multiple Myeloma Use Case

Synthetic Data generation

- Data have been generated through a Variational AutoEncoder (VAE) based model to train 15 different seeds, since variability on results depends on the initial conditions. The model is also able to generate a missing values mask by learning the real distribution of missing values, useful to create later scenarios with incomplete data

	Avg. accuracy / Avg. F1-score	Three best seeds accuracies with Confidence Intervals	Three best seeds average F1-Score
Complete data	0.645 / 0.645	0.5867 - 0.6261 - 0.6643	0.621
		0.6073 - 0.6464 - 0.684	0.6503
		0.6234 - 0.6622 - 0.6994	0.6652
Missing values mask	0.506 / 0.267	0.4644 - 0.5045 - 0.5445	0.3678
		0.4667 - 0.5068 - 0.5468	0.0891
		4667 - 0.5068 - 0.5468	0.344
Complete data + Missing values mask	0.655 / 0.649	0.6119 - 0.6509 - 0.6884	0.6437
		0.6165 - 0.6554 - 0.6928	0.6434
		0.6188 - 0.6577 - 0.695	0.6607
Incomplete data	0.642 / 0.640	0.6004 - 0.6396 - 0.6774	0.6347
		0.6027 - 0.6419 - 0.6797	0.6241
		0.605 - 0.6441 - 0.6818	0.6609

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Synthetic Data validation

- Utility validation with a Survival Analysis (whose metric is the C-Index) and a Classification task predicting the Early Relapse (whose metric is the classification accuracy), taking into account also of the use of complete or incomplete data

	SURVIVAL ANALYSIS		CLASSIFICATION	
Type of generated data	Avg. C-index	Three best seeds C-index (real data training - synthetic data training)	Avg. accuracy	Three best seeds accuracies (real data training - synthetic data training)
Complete data	0.607	0.62 - 0.62	0.574	0.61 - 0.57
		0.62 - 0.61		0.57 - 0.55
		0.62 - 0.59		0.56 - 0.61
Incomplete data	0.615	0.62 - 0.61	0.572	0.58 – 0.55
		0.62 - 0.62		0.61 – 0.58
		0.62 - 0.61		0.55 – 0.58

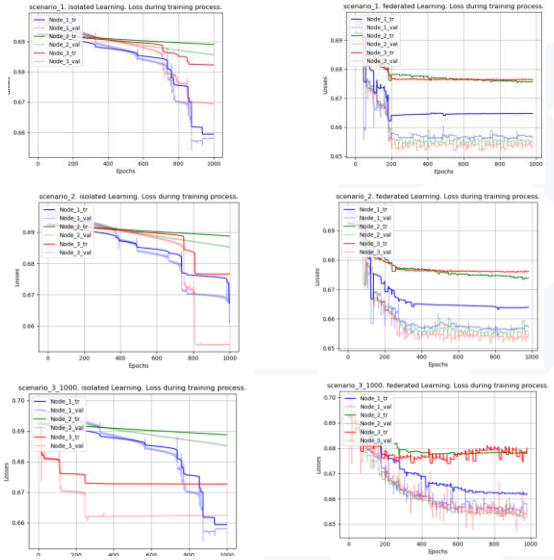
- Training with synthetic data gives similar results to training with real data, indicating that the generated data is valid from the utility point of view

GenoMed4All: Multiple Myeloma Use Case

Validation protocol scenarios

- This protocol will be carried out to see the performance of the model in simulations with different quantities and qualities of data

Scenarios	Nodes	# of samples	F1 score - ISOLATED	F1 score - FEDERATED
Centralized	Node_1	6000	(0.331, 0.3522, 0.3739)	-
Scenario 1	Node_1	2000	(0.321, 0.342, 0.3635)	(0.3301, 0.3513, 0.373)
	Node_2	2000	(0.3174, 0.3384, 0.3599)	(0.3235, 0.3446, 0.3662)
	Node_3	2000	(0.3073, 0.3281, 0.3494)	(0.3179, 0.3389, 0.3604)
Scenario 2	Node_1	2000	(0.3336, 0.3548, 0.3765)	(0.3287, 0.3499, 0.3715)
	Node_2	2000	(0.3199, 0.3409, 0.3624)	(0.3208, 0.3418, 0.3633)
	Node_3	2000	(0.3212, 0.3422, 0.3637)	(0.3249, 0.346, 0.3676)
Scenario 3_10	Node_1	2000	(0.321, 0.342, 0.3635)	(0.3277, 0.3489, 0.3705)
	Node_2	2000	(0.3199, 0.3409, 0.3624)	(0.333, 0.3542, 0.3759)
	Node_3	10	(0.2389, 0.2582, 0.2783)	**(0.2987, 0.3193, 0.3405)**
Scenario 3_50	Node_1	2000	(0.321, 0.342, 0.3635)	(0.3269, 0.348, 0.3696)
	Node_2	2000	(0.3199, 0.3409, 0.3624)	(0.327, 0.3481, 0.3697)
	Node_3	50	(0.2426, 0.262, 0.2821)	**(0.3231, 0.3442, 0.3658)**
Scenario 3_100	Node_1	2000	(0.321, 0.342, 0.3635)	(0.3294, 0.3506, 0.3722)
	Node_2	2000	(0.3199, 0.3409, 0.3624)	(0.3293, 0.3505, 0.3721)
	Node_3	100	(0.1351, 0.1507, 0.1674)	**(0.304, 0.3247, 0.346)**
Scenario 3_500	Node_1	2000	(0.321, 0.342, 0.3635)	(0.3304, 0.3516, 0.3733)
	Node_2	2000	(0.3199, 0.3409, 0.3624)	(0.328, 0.3492, 0.3708)
	Node_3	500	(0.3034, 0.3241, 0.3454)	(0.3304, 0.3516, 0.3733)
Scenario 3_1000	Node_1	2000	(0.321, 0.342, 0.3635)	(0.3241, 0.3452, 0.3668)
	Node_2	2000	(0.3199, 0.3409, 0.3624)	(0.3269, 0.348, 0.3696)
	Node_3	1000	(0.307, 0.3278, 0.3491)	(0.3262, 0.3473, 0.3689)



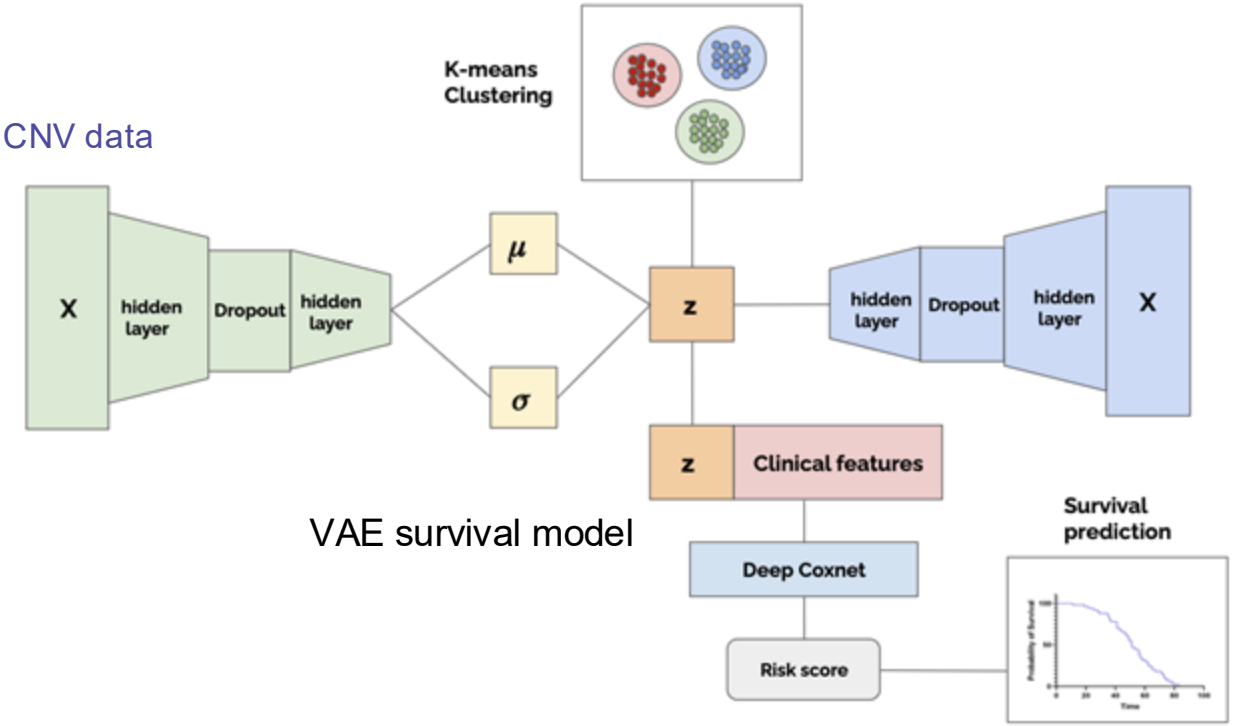
- FL achieves F1-Score results statistically indistinguishable from the Centralized case
- FL is specially recommended in settings where some nodes do have few samples (scenario 3)

GenoMed4All: Multiple Myeloma Use Case

Data modelling for risk prediction

Clinical features (11):

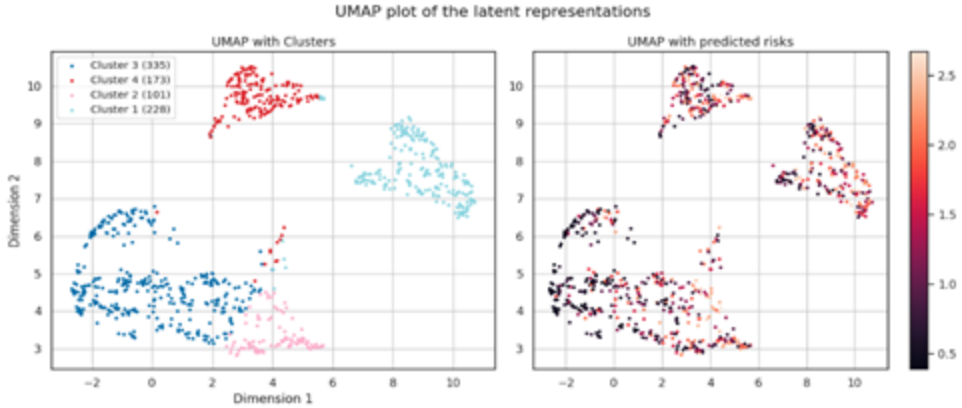
- Age
- Sex
- FISH_T_11_14
- Creatinine
- HB
- PLT
- Calcium
- tx
- rss
- light_chain
- R_ISS



GenoMed4All: Multiple Myeloma Use Case

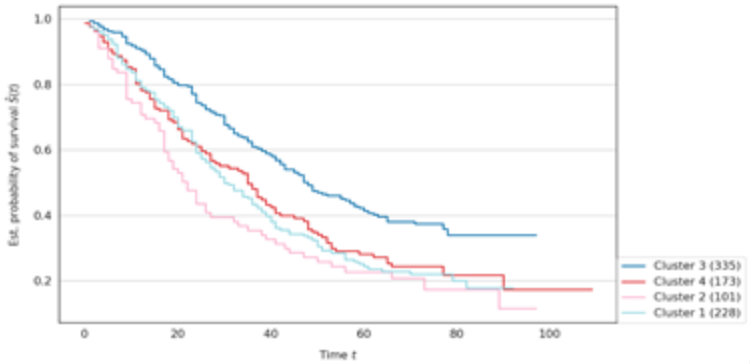
Data modelling for risk prediction

CoMMpass (837 patients)



C-Index cross-validation:

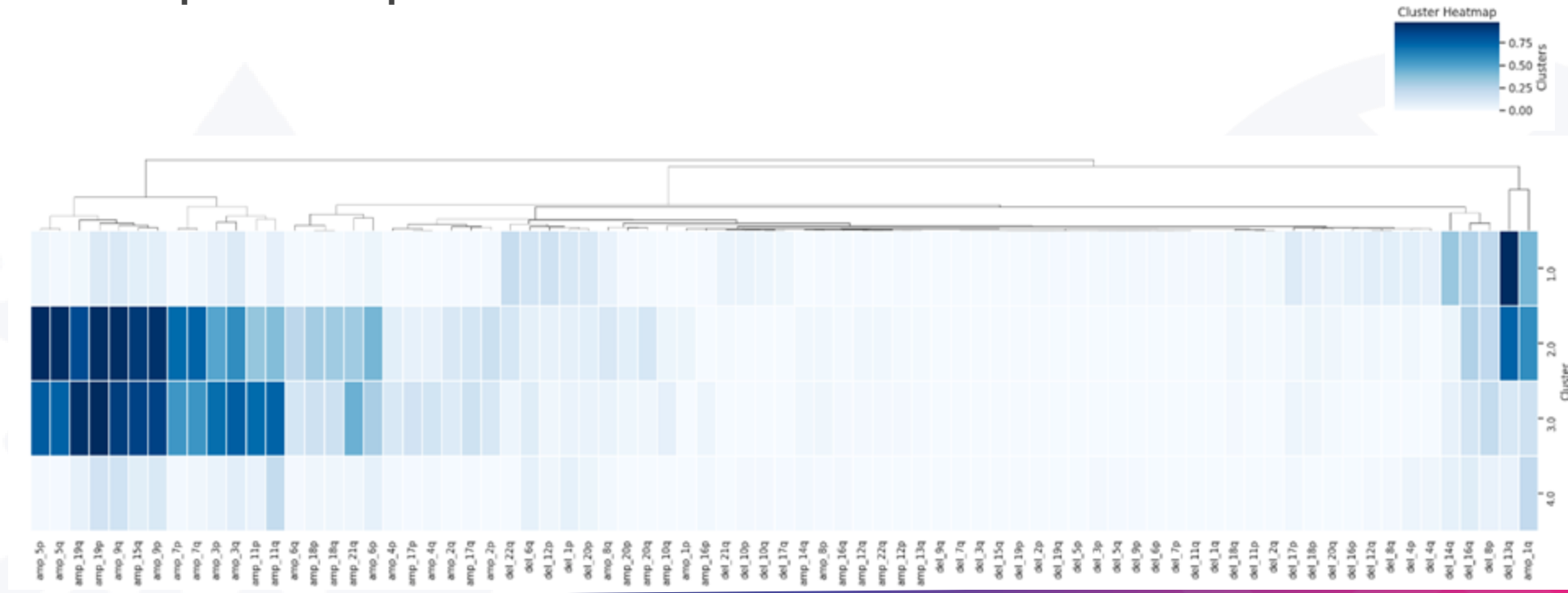
0.70±0.02



GenoMed4All: Multiple Myeloma Use Case

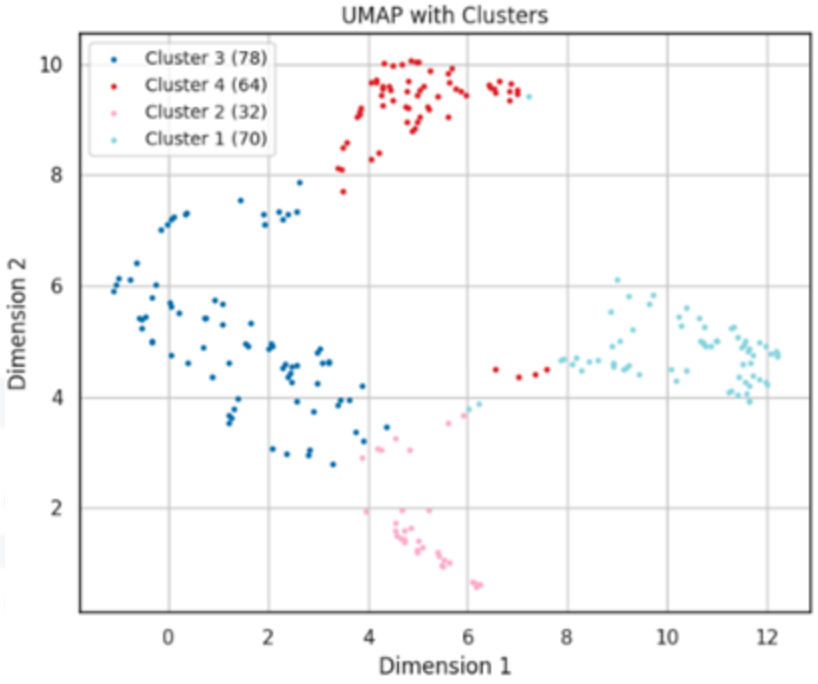
Data modelling for risk prediction

CoMMpass: CNV patterns across different clusters



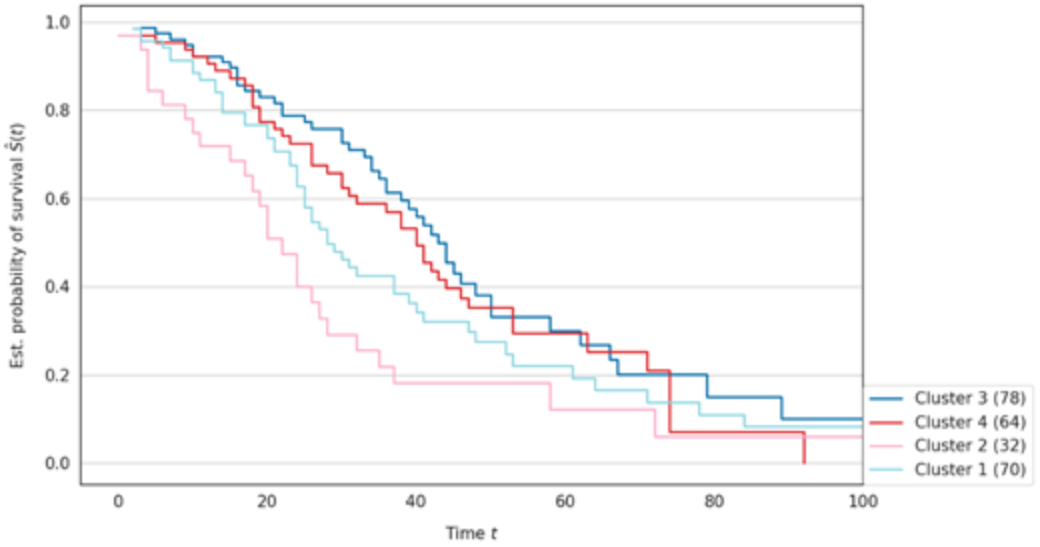
GenoMed4All: Multiple Myeloma Use Case

Data modelling for risk prediction



Bologna (253 patients → 244)

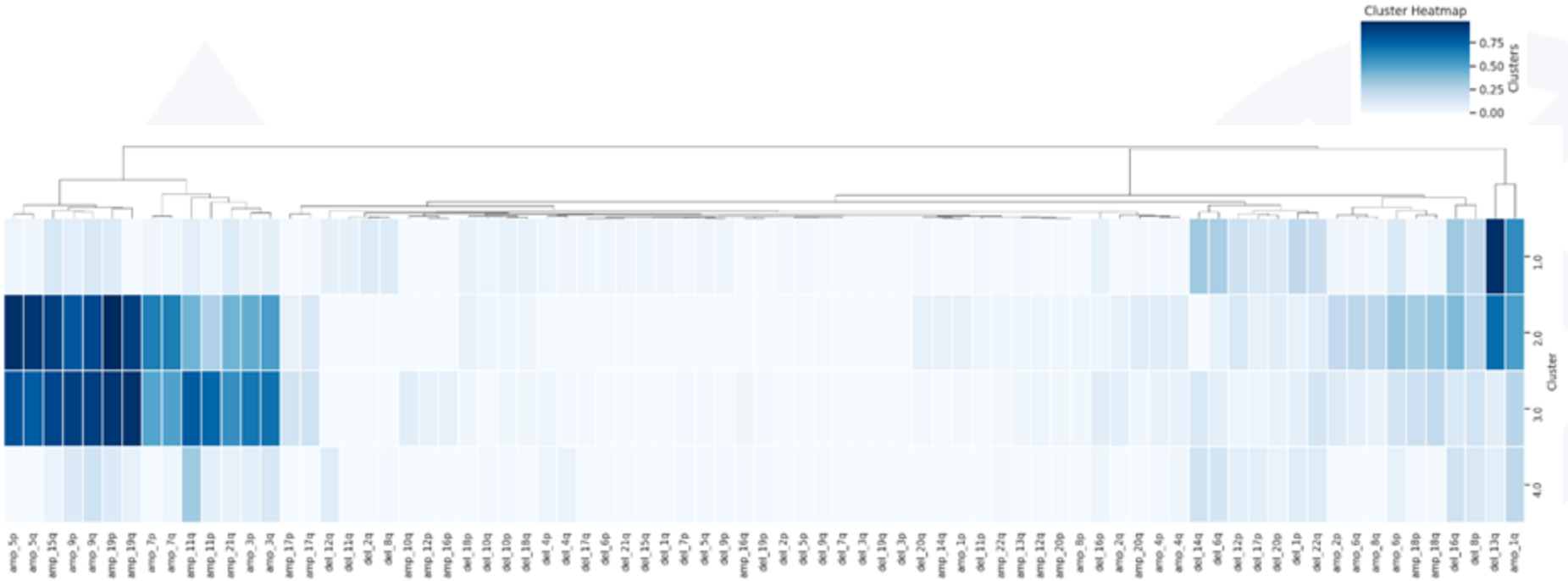
C-Index : 0.69



GenoMed4All: Multiple Myeloma Use Case

Data modelling for risk prediction

Bologna dataset: CNV patterns across different clusters

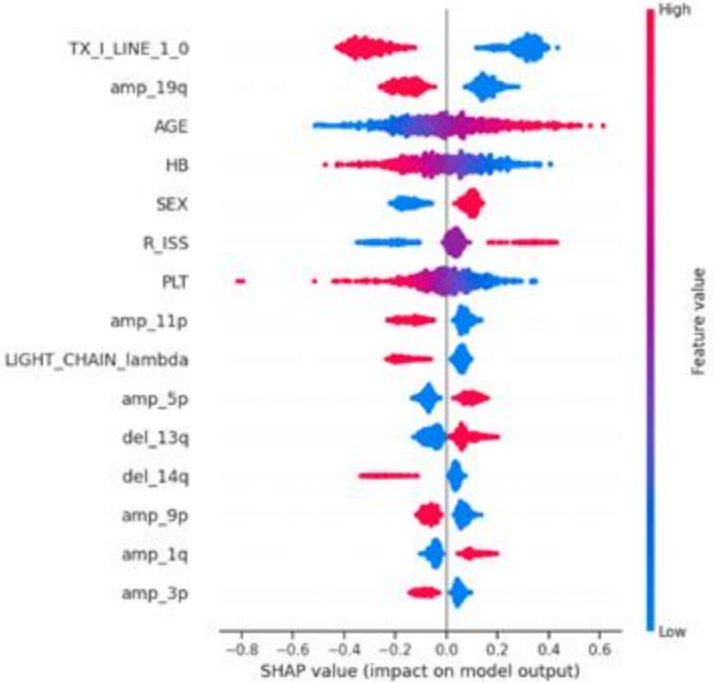


GenoMed4All: Multiple Myeloma Use Case

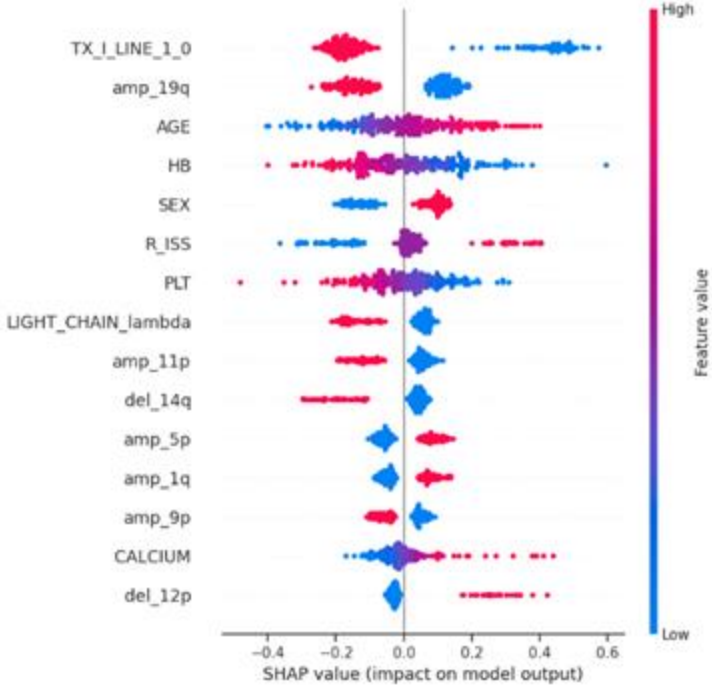
Data modelling for risk prediction

Features importance with SHAP Explainability

CoMMpass



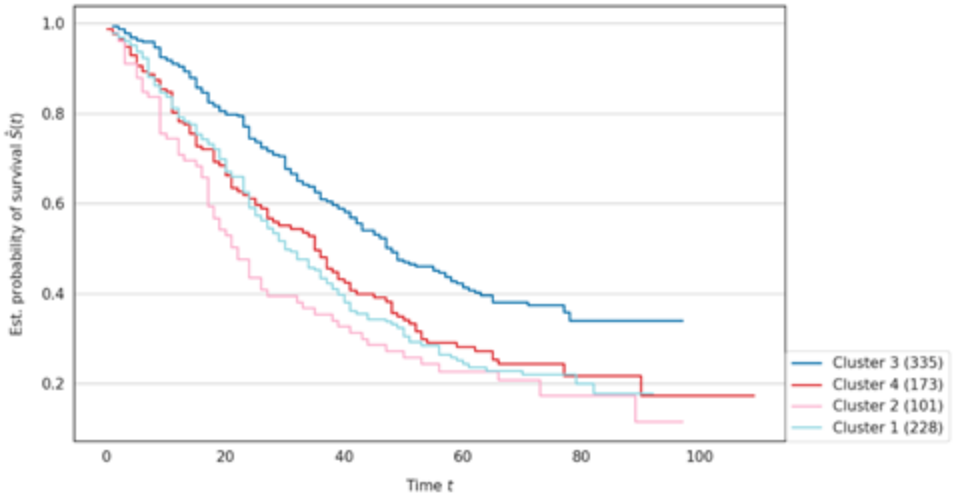
Bologna



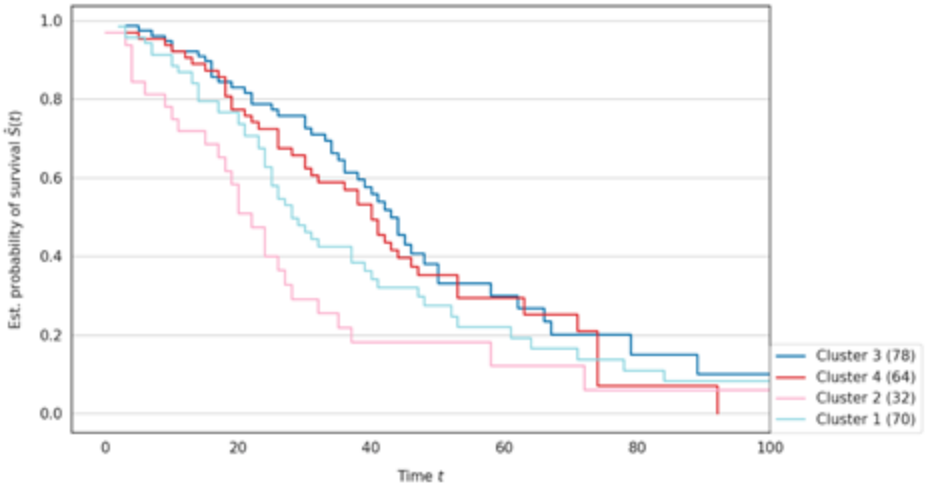
GenoMed4All: Multiple Myeloma Use Case

Data modelling for risk prediction

COMMPASS



GenoMed



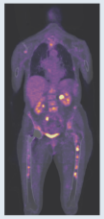
GenoMed4All: Multiple Myeloma Use Case

Radiomics

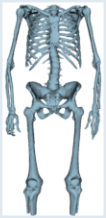
1 - Data selection

- Imaging protocol: 18F-FDG PET/CT
- VOIs selection: skeleton & paraskeletal structures
- Clinical data: prediction target

2 - Image processing



- Multimodal intra-subject image registration
- Dose correction (PET images)



- Segmentation of VOIs from CT images
- Volume cropping

3 - Feature extraction

- Image filtering: original, wavelet, LoG

Feature extraction

- 1st order
- shape
- texture

pyradiomics

4 - Survival analysis

- Pre-processing of features: scaling

Modelling

- Cox model with L1 regularisation (LASSO)
- Nested cross-validation

- Evaluation of model performance

GenoMed4All: Multiple Myeloma Use Case

Radiomics: current status

Dataset

- 214 MM patients (Sant'Orsola Hospital, BO)
- Clinical endpoints: Progression-Free Survival (PFS), Overall Survival (OS)

Image processing

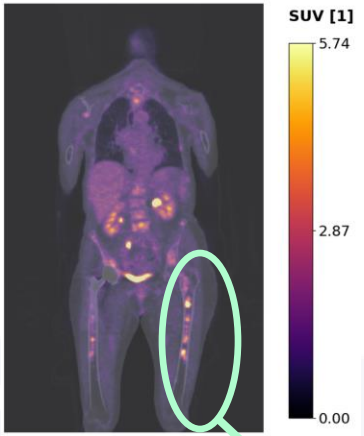
- Intra-patient image registration
- Dose correction on PET images ⟶ SUV
- Volume cropping (no brain, homogeneous FOV)
- Segmentation of Volumes of Interest (VOI)

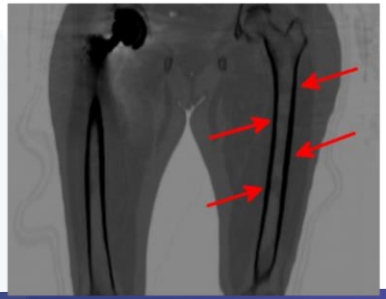
Segmentation method: semantic segmentation

VOI: whole skeleton

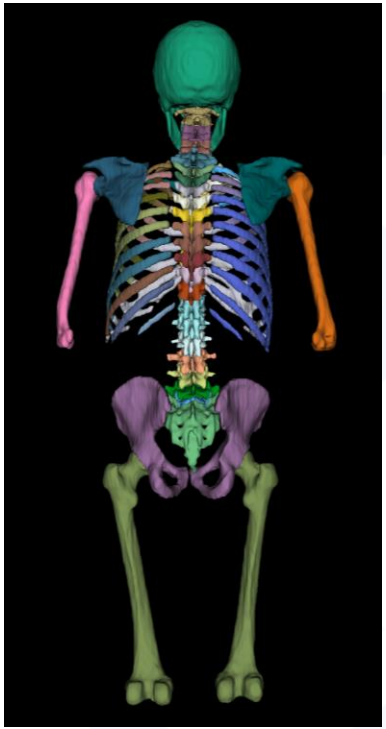
GenoMed4All: Multiple Myeloma Use Case

Radiomics: current status





- Registered PET/CT images
- Dose-corrected PET
- Osteolytic lesions visible in both imaging modalities (example: in femur)
- Segmentation of skeleton
- Extraction of radiomic features



Multiple Myeloma CLINICS&BIOLOGY

The Genomed4All project: Multiple Myeloma use case WRAP-UP

- Multiple Myeloma is a COMPLEX disease, but still needs a CURE
- Strong need to interconnect CLINICS & BIOLOGY to better predict PATIENTS' RISK
- A precise PREDICTION requires HUGE AMOUNT OF (CURATED) DATA to be statistically significative and clinically meaningful
- ARTIFICIAL INTELLIGENCE can help in data management, interconnection and prediction
- With our partners in the GENOMED4ALL project we aimed at the integration of both CLINICAL, GENOMIC and IMAGING of a large cohort of newly diagnosed MM patients in order to identify PREDICTORS OF EARLY RELAPSE that can refine the definition of high risk patients
- In the FUTURE, these results will contribute to an IMPROVED DESIGN of clinical trials and a BETTER PATIENTS' MANAGEMENT, towards a more PRECISE MEDICINE

ACKNOWLEDGEMENTS

Multiple Myeloma Research Unit
Prof. Michele Cavo

MOLECULAR BIOLOGY LAB
Carolina Terragna
Marina Martello
Enrica Borsi
Silvia Armuzzi
Ilaria Vigliotta
Barbara Taurisano
Ignazia Pistis
Alessia Varacalli
Alessia Croce

BIOINFO NERDs
Vincenza Solli
Andrea Poletti
Gaia Mazzocchetti
Viola Mieaxian Vuong

CLINICAL RESEARCH UNIT
Elena Zamagni
Paola Tacchetti
Lucia Pantani
Katia Mancuso
Ilaria Rizzello
Chiara Sartor
Miriam Iezza
Marco Talarico
Michele Puppi
Flavia Bigi
Ilaria Sacchetti
Enrica Manzato
Simone Masci
Roberta Restuccia

CYTOGENETIC LAB
Nicoletta Testoni
Giulia Marzocchi

DATA ANALYSIS and MANAGEMENT
Simona Barbato
Francesca Trombetta
Federica Di Camillo

NUCLEAR MEDICINE
Cristina Nanni

Gastone Castellani
Claudia Sala
Francesco Durazzi
Alessandra Merlotti
Sara Peluso
Enrico Giampieri
Stefano Polizzi
Martina Tarozzi

Santiago Zazo Bello
Juan Parras Moral
Patricia Alonso

Piero Fariselli
Cesare Rollo
Tiziana Sanavia

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Horizon 2020
European Union Funding
for Research & Innovation

SERVIZIO SANITARIO REGIONALE
EMILIA-ROMAGNA
Azienda Ospedaliero - Universitaria di Bologna
IRCCS Istituto di Ricovero e Cura a Carattere Scientifico

POLICLINICO DI SANT'ORSOLA

International Myeloma Society

MMRF MULTIPLE MYELOMA Research Foundation

AIL Bologna

AIRC ASSOCIAZIONE ITALIANA PER LA RICERCA SUL CANCRO

Banca di Bologna

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Thanks!

Any questions?

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Educational Program on AI in Hematology for an expert audience

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Acknowledgements

European Reference Network
for rare or low prevalence complex diseases
Network Hematological Diseases (ERN EuroBloodNet)

Co-funded by the European Union

This project is supported by the European Reference Network on Rare Haematological Diseases (ERN-EuroBloodNet)-Project ID No 101085717. ERN-EuroBloodNet is partly co-funded by the European Union within the framework of the Fourth EU Health Programme.

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or European Health and Digital Executive Agency (HaDEA). Neither the European Union nor the granting authority can be held responsible for them.

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Funded by the European Union

GenoMed4All has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101017549.