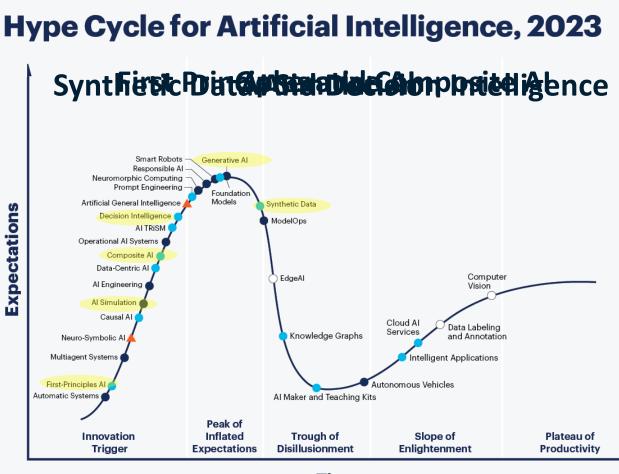
# Artificial Intelligence and Analytics Trends

• John Gottula Director of Crop Science SAS





Time

Plateau will be reached:

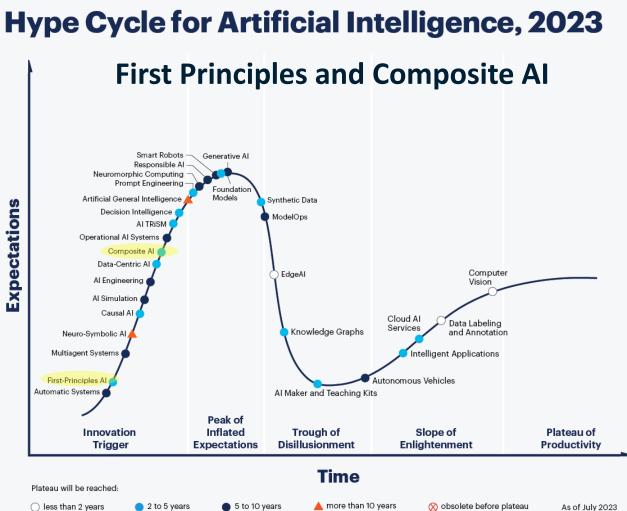
less than 2 years

5 to 10 years

2 to 5 years

🔺 more than 10 years

🚫 obsolete before plateau



# **Crop Composition Data for EU Regulatory Submission**

#### REGULATIONS

#### COMMISSION IMPLEMENTING REGULATION (EU) No 503/2013

#### of 3 April 2013

on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006



Statistical considerations for GMOs safety

SCIENTIFIC OPINION

Scientific Opinion on

Statistical considerations for the safety evaluation of GMOs

EFSA Panel on Genetically Modified Organisms (GMO)<sup>2,3</sup>

European Food Safety Authority (EFSA), Parma, Italy



#### SCIENTIFIC OPINION

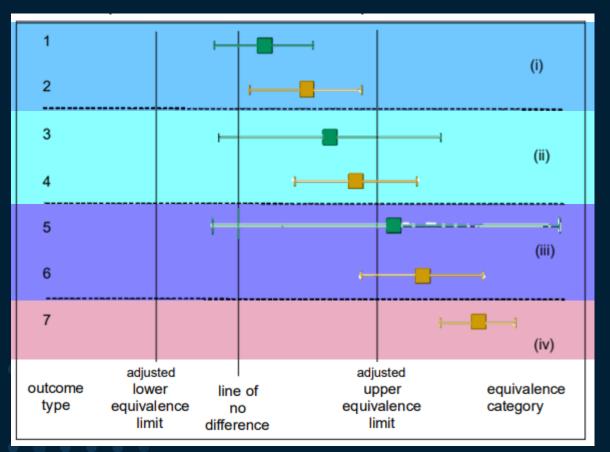
Guidance for risk assessment of food and feed from genetically modified plants<sup>1</sup>

EFSA Panel on Genetically Modified Organisms (GMO)<sup>2,3</sup> European Food Safety Authority (EFSA), Parma, Italy

A	В	С	D	E	F	G	Н	<u>н</u> ,	L
Analyte Categ 💌	analyte 💌	it of Me 💌	genoty 💌	Backgroun 💌	genoty 💌	notype 🔽	rep 💌	site 💌	у 💌
Amino Acids	Alanine	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	1	Atlantic, IA	5.65
Amino Acids	Alanine	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	2	Atlantic, IA	5.29
Amino Acids	Alanine	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	3	Atlantic, IA	5.14
Amino Acids	Alanine	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	4	Atlantic, IA	5.71
Amino Acids	Arginine	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	1	Atlantic, IA	3.17
Amino Acids	Arginine	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	2	Atlantic, IA	2.88
Amino Acids	Arginine	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	3	Atlantic, IA	3.02
Amino Acids	Arginine	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	4	Atlantic, IA	3.25
Amino Acids	Aspartic Acid	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	1	Atlantic, IA	4.67
Amino Acids	Aspartic Acid	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	2	Atlantic, IA	4.62
Amino Acids	Aspartic Acid	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	3	Atlantic, IA	4.11
Amino Acids	Aspartic Acid	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	4	Atlantic, IA	4.53
Amino Acids	Cystine	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	1	Atlantic, IA	1.55
Amino Acids	Cystine	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	2	Atlantic, IA	1.53
Amino Acids	Cystine	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	3	Atlantic, IA	1.43
Amino Acids	Cystine	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	4	Atlantic, IA	1.49
Amino Acids	Glutamic Acid	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	1	Atlantic, IA	14.29
Amino Acids	Glutamic Acid	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	2	Atlantic, IA	13.49
Amino Acids	Glutamic Acid	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	3	Atlantic, IA	13.04
Amino Acids	Glutamic Acid	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	4	Atlantic, IA	13.70
Amino Acids	Glycine	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	1	Atlantic, IA	2.72
Amino Acids	Glycine	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	2	Atlantic, IA	2.57
Amino Acids	Glycine	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	3	Atlantic, IA	2.50
Amino Acids	Glycine	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	4	Atlantic, IA	2.53
Amino Acids	Histidine	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	1	Atlantic, IA	2.17
Amino Acids	Histidine	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	2	Atlantic, IA	2.07
Amino Acids	Histidine	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	3	Atlantic, IA	1.96
Amino Acids	Histidine	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	4	Atlantic, IA	2.20
Amino Acids	Isoleucine	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	1	Atlantic, IA	2.58
Amino Acids	Isoleucine	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	2	Atlantic, IA	2.47
Amino Acids	Isoleucine	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	3	Atlantic, IA	2.29
Amino Acids	Isoleucine	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	4	Atlantic, IA	2.14
Amino Acids	Leucine	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	1	Atlantic, IA	9.61
Amino Acids	Leucine	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	2	Atlantic, IA	9.08
Amino Acids	Leucine	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	3	Atlantic, IA	8.78
Amino Acids	Leucine	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	4	Atlantic, IA	9.56
Amino Acids	Lysine	mg/g DW	Comp	omp Backgroun	Non-GM	Comp	1	Atlantic, IA	2.30



# **EFSA Difference and Equivalence**

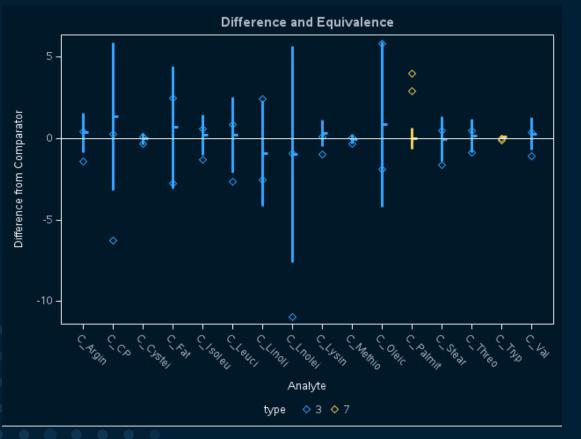


Compared to comparator: No difference Difference

Compared to references: Equivalent Likely Equivalent Less Likely Equivalent Not Equivalent

S.sas

# **Common flaws to implement EFSA's approach**



- Comparator's genetic composition not equivalent to GMO
- Reference varieties do not capture adequate range of diversity
- Reference varieties different from Comparator



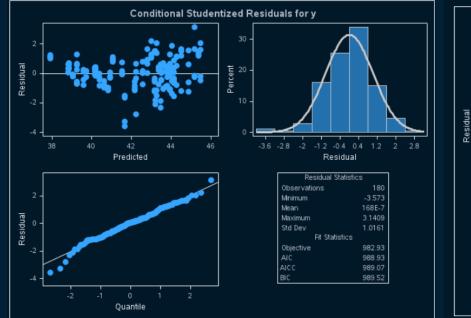
# **Composite AI – "Self-Service" Analytics**

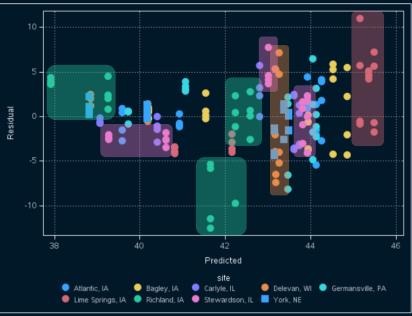
Des       Model Options Output Information       Code Log Results OutputDes(1)	🛧 Run 🛛 Cancel 🛛 🖞 🖪 🖪 🖉 Copy to My Tasks 🛛 🕂 Code to Flow 🔻		Oct 9, 2023, 1:37:22 PM 📄 (0)
WORK.COMPSTUDY1   V   V Filter:   Image: construction of the state of	Deta Model Options Output Information	Code Log	g Results Output Deta (1) 🖍 Edit Code 🗆 🗄
	WORK.COMPSTUDY1   V   Filter:   none      V   Roles   Dependent variable:                                   V   Roles   Dependent variable:   V   Roles                       V       V       V	$3$ $4$ $5$ $6$ $7$ $8$ $9$ $10$ $11$ $12$ $13$ $14$ $\Theta$ $15$ $16$ $17$ $18$ $\Theta$ $19$ $20$ $21$ $22$ $23$ $24$ $25$ $26$ $\Theta$	<pre>* * Generated on '10/9/23, 1:38 PM' * Generated on SAS version 'V.04.00M0P091823' * Generated on SAS version 'V.04.00M0P091823' * Generated on browser 'Mozilla/5.0 (Windows NT 10.0; Win64; x64) AppleWebKit/537.36 (KHTML, * Generated on web client 'https://agtech2-viya4.eastus2.cloudapp.azure.com/SASStudio/main?lo */ ods noproctitle; ods graphics / imagemap=on;  proc sort data=WORK.COMPSTUDY1 out=Worktempsorted_;     by Analyte; run;  proc mixed data=Worktempsorted_ method=rem1 alpha=0.1;     class genotype rep site Background genotypegroup;     model y=genotypegroup / ddfm=kenog;     random rep site rep*site genotype*Background /;     weight InverseCv;     by Analyte; run;  proc delete data=Worktempsorted_; </pre>

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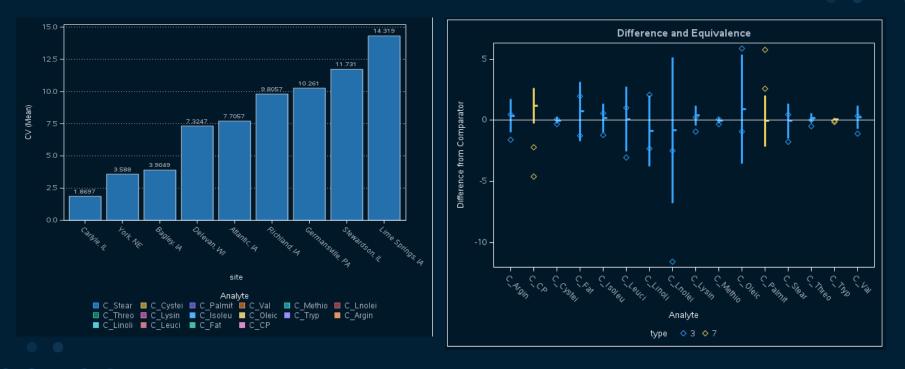
# **First Principles AI – Thinking Through the Question**







# **Quantifying and Weighting Errors**



• • • • • • • • • • • • • • •



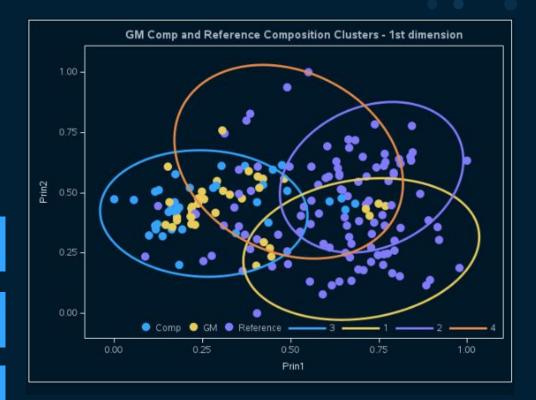
# Analyzing Composition Components All at Once?

- Composition endpoints are structurally related
- Composition endpoints have correlated errors
- Independent Analysis of each results in a Multiple Testing Problem

Distill each endpoint into few information rich vectors (e.g. Principal Components)

Generate Clusters among observations

Test GM for 'cluster belonging' and withincluster variance





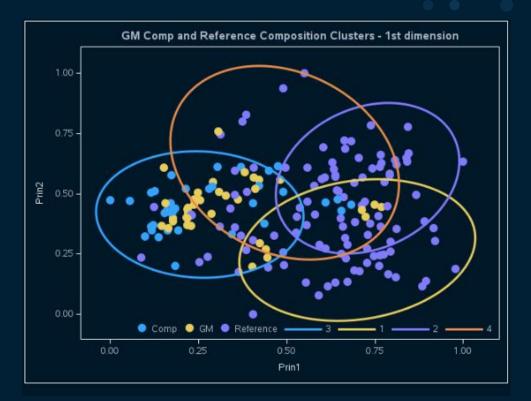
# **Cluster-based Difference Testing**

# Difference: Does the GM cluster with its comparator? $(x^2)$

Frequency	Table of genotypegroup by CLUSTER												
Row Pct		CLUSTER(Cluster)											
	genotypegroup	1	2	3	4	Total							
	Comp	0 0.00	4 11.11	26 72.22	6 16.67	36							
	GM	3 8.33	1 2.78	29 80.56	3 8.33	36							
	Total	3	5	55	9	72							

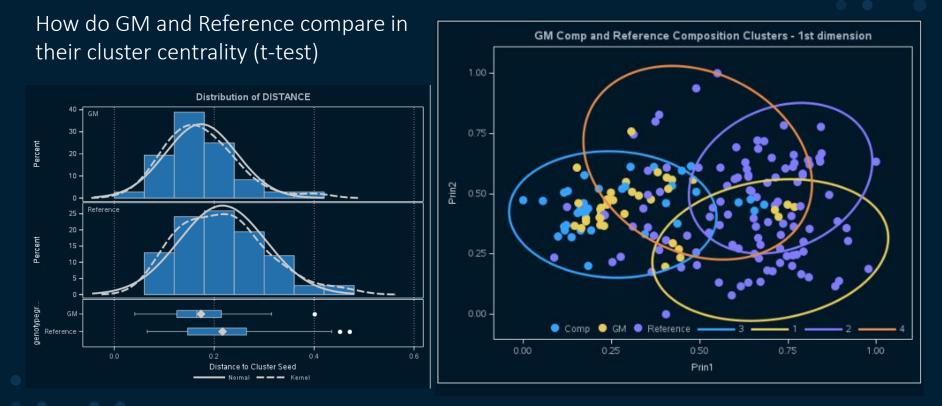
#### Statistics for Table of genotypegroup by CLUSTER

Statistic	DF	Value	Prob
Chi-Square	3	5.9636	0.1134
Likelihood Ratio Chi-Square	3	7.2694	0.0638
Mantel-Haenszel Chi-Square	1	1.3683	0.2421
Phi Coefficient		0.2878	
Contingency Coefficient		0.2766	
Cramer's V		0.2878	





# **Cluster-based Equivalence Testing**

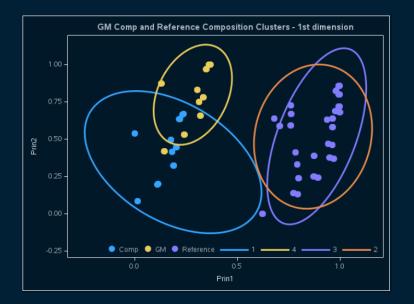


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# **First Principles and Composite AI**

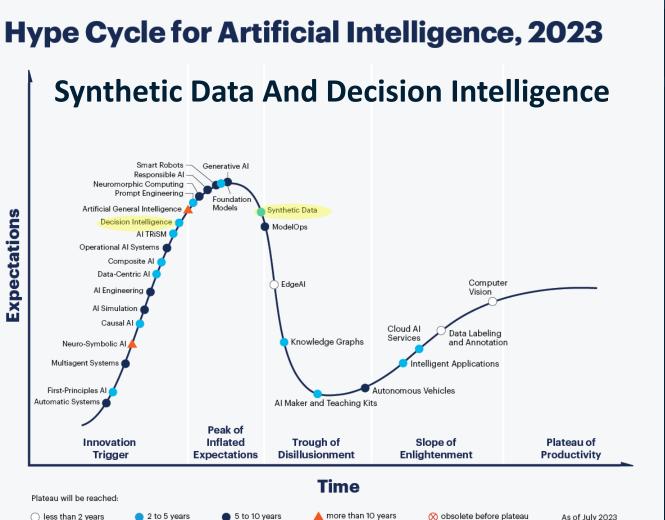
Applied to EFSA Difference and Equivalence Testing

- Self-service data analysis crucial for frontline business and scientific decisions
- Data generators possess invaluable understanding of data (and error) generation process
- Site-Analyte inverse variance weighting leads to less equivalence (and probably more differences)
- Clustering and cluster statistics can test wholistic GMO compositional difference and equivalence



Clustering following best linear unbiased estimates of each site\*analyte combo





As of July 2023

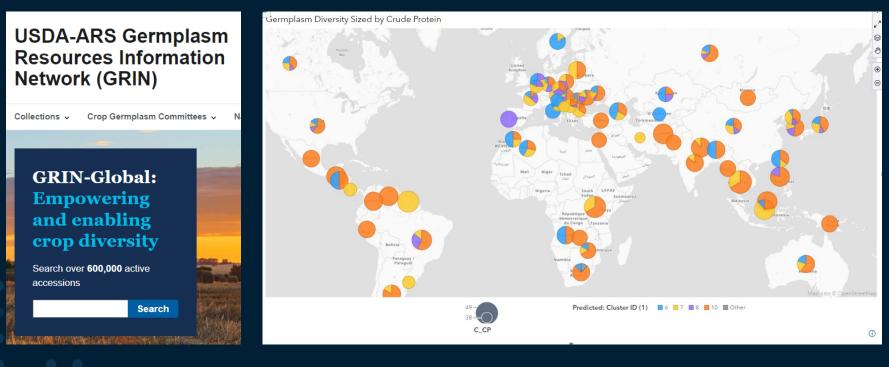
less than 2 years

🔵 2 to 5 years

🔵 5 to 10 years

# **USDA Germplasm Resources**

## If your reference varieties aren't working, change them!





# Germplasm Phenotypes $\rightarrow$ case for synthetic data

### Before

	6	6				IZ.			N	0			
A	С	G	н		J	K	L	M	N	0	D_Access	D_Orig	C_A
D_Access		C_Argin	C_Cystei	C_lsoleu	C_Leuci	C_Lysin	_	C_Threo	C_Tryp	C_Val	FC 31557	United Sta	а
FC 31557	United State						15.2				FC 31579	Illinois, Ur	n
FC 31579	Illinois, Unit										FC 32141	South Dal	¢
FC 32141	South Dako	7.5	1.5	4.6	8	6.5			1.4	5	PI 189926	United Sta	а
PI 189926	United State	es					15				PI 248398	Illinois, U	n
PI 248398	Illinois, Unit	ed States										Illinois, U	
PI 248402	Illinois, Unit	ted States					10.7					Hawaii, U	
PI 355067	Hawaii, Uni	ted States					11.2						
PI 355068	Hawaii, Uni	ted States					11.5					Hawaii, U	
PI 404154	United State	7.57	1.45	4.55	7.87	6.44	11.3	3.58	1.19	5.18		United Sta	
PI 417576	United State	es					13					United Sta	_
PI 417579	United State	6.9	2	5.5	8.3	6.1	12.05	3.3	1.2	4.9	PI 417579	United Sta	а
PI 417582	United State	7.4	1.7	5.1	7.9	6.6	11.9	3.6	1.5	5.2	PI 417582	United Sta	а
PI 438492	United State	es					12.8				PI 438492	United Sta	а
PI 438493	United State	es					12.3				PI 438493	United Sta	a
PI 438494	United State	7.4	1.5	4.4	7.5	6.2	11.45	3.6	1.3	5	PI 438494	United Sta	а
PI 438500	United State	7.3	1.4	5.4	8.1	6.7	10.95	3.5	1.2	4.6	PI 438500	United Sta	a
PI 506417	Illinois, Unit	7.6	1.5	5.1	8	7	10.5	3.8	1.2	5	PI 506417	Illinois, U	n
PI 508083	Minnesota,	7.5	1.6	5	8.1	6.8	10.25	3.9	1.3	5.2	PI 508083	Minnesot	a
PI 508084	Minnesota,	7.3	1.5	4.5	7.6	6.3	11.55	3.7	1.3	5	PI 508084	Minnesot	a
PI 508266	North Carol	7.6	1.6	4.9	7.7	6.5	12.34	3.6	1.3	5.1	PI 508266	North Car	c
PI 508268	Virginia, Un	7.7	1.7	4.9	8.2	6.6	11.9	3.8	1.4	5.3	PI 508268	Virginia, U	J
<u>PI 508</u> 269	Virginia, Un	ited States					10.5				PI 508269	Virginia, L	J

_Access	D_Orig	C_Argin	C_Cystei	C_lsoleu	C_Leuci	C_Lysin	C_Palmit	C_Threo	C_Tryp	C_Val
C 31557	United Sta	7.43	1.35	4.7	7.94	6.42	15.2	3.59	1.28	4.89
C 31579	Illinois, Un	7.48	1.48	4.6	7.84	6.59	10.4	3.67	1.16	5.15
C 32141	South Dak	7.5	1.5	4.6	8	6.5	11.5	3.7	1.4	5
189926	United Sta	7.69	1.55	4.77	8.04	6.9	15	3.61	1.35	4.92
1 248398	Illinois, Un	7.15	1.43	4.35	7.84	5.96	12.57842	3.57	1.27	4.88
1 248402	Illinois, Un	7.35	1.59	4.58	7.88	6.8	10.7	3.89	1.32	4.97
1 355067	Hawaii, Ur	7.62	1.41	4.45	7.55	6.23	11.2	3.39	1.13	4.62
1 355068	Hawaii, Ur	7.48	1.44	4.42	7.45	6.17	11.5	3.38	1.21	4.85
1 404154	United Sta	7.57	1.45	4.55	7.87	6.44	11.3	3.58	1.19	5.18
1 417576	United Sta	7.53	1.49	4.97	8.28	6.27	13	3.46	1.33	4.98
417579	United Sta	6.9	2	5.5	8.3	6.1	12.05	3.3	1.2	4.9
1 417582	United Sta	7.4	1.7	5.1	7.9	6.6	11.9	3.6	1.5	5.2
1 438492	United Sta	7.46	1.46	4.77	8.08	6.11	12.8	3.52	1.32	4.99
1 438493	United Sta	7.5	1.55	4.75	7.94	6.44	12.3	3.67	1.28	5.07
1 438494	United Sta	7.4	1.5	4.4	7.5	6.2	11.45	3.6	1.3	5
1 438500	United Sta	7.3	1.4	5.4	8.1	6.7	10.95	3.5	1.2	4.6
1 506417	Illinois, Un	7.6	1.5	5.1	8	7	10.5	3.8	1.2	5
1 508083	Minnesota	7.5	1.6	5	8.1	6.8	10.25	3.9	1.3	5.2
1 508084	Minnesota	7.3	1.5	4.5	7.6	6.3	11.55	3.7	1.3	5
1 508266	North Card	7.6	1.6	4.9	7.7	6.5	12.34	3.6	1.3	5.1
1 508268	Virginia, U	7.7	1.7	4.9	8.2	6.6	11.9	3.8	1.4	5.3
1508269	Virginia, U	7.63	1.45	5.41	8.29	6.31	10.5	3.73	1.37	4.98

After

Imputation can backtrack the most likely values in sparse data sets

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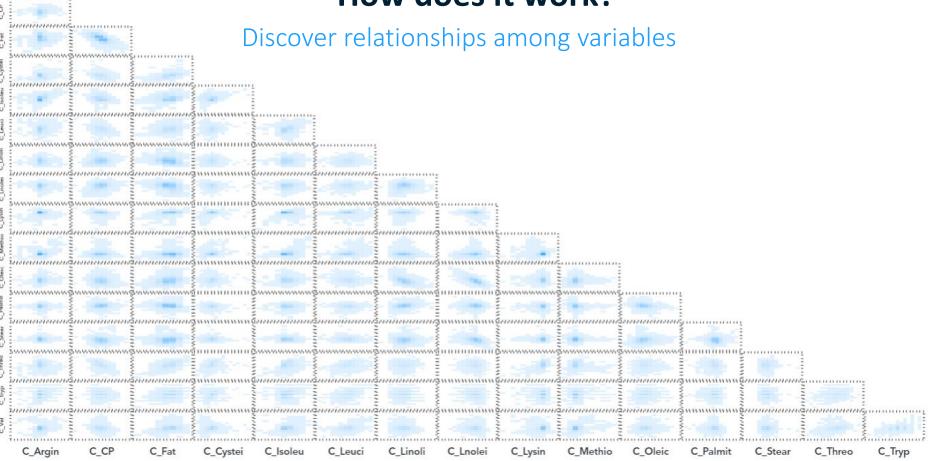
#### Correlations

......



# How does it work?

....

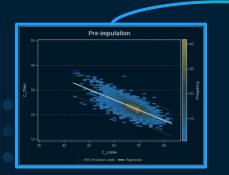


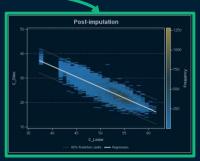
# **Evaluating Synthetic Data Validity**

#### C\_Fat C\_Isoleu C\_Leuci C\_Linoli C\_Lnolei C\_Lysin C\_Methio C\_Oleic C\_Palmit C\_Stear C\_Three C\_Tryp Group C Argin C CP C Cystei C\_Val Freq 1 X 2066 2. Х Х 521 Х 3. Х Х 316 4. 2013 Х 5. Х Х Х 18 6. 4 7 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 91

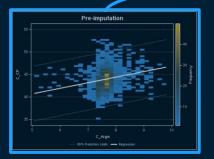
### Is there sufficient mutual information?

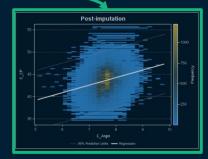
### Are the output relationships reasonable?





Linoleic vs Oleic





#### Arginine vs Crude Protein



# **Decision Intelligence**

### Identify important variables

### Assess scenarios

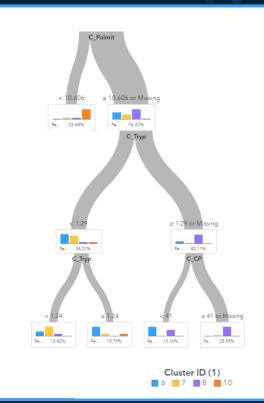
### Undertake classification



Cluster ID (1) 🔺	D_Orig	High_Yield	MG3	 D_Access	C_Tryp	C_CP	C_Palmit	P_Mdate	P_SWght
6	Illinois, United States	High_Yield	MG3	PI 548628	1.29	43	12.15	1002	19
6	Iowa, United States	High_Yield	MG3	PI 548543	1.27	43	10.9	927	20
6	Ohio, United States	High_Yield	MG3	PI 584470	1.24	44	12	925	23
6	Nebraska, United States	High_Yield	MG3	PI 595754	1.30	41	10.65	928	16
6	United States	High_Yield	MG3	PI 404154	1.19	44	11.3	923	16
7	Illinois, United States	High_Yield	MG3	PI 597385	1.20	42	11.8	919	16
8	Illinois, United States	High_Yield	MG3	PI 518675	1.30	42	11.85	912	15
8	Ohio, United States	High_Yield	MG3	PI 567902	1.40	42	11.1	929	16
8	Nebraska, United States	High_Yield	MG3	PI 610670	1.37	41	10.65	924	17
8	Nebraska, United States	High_Yield	MG3	PI 595753	1.40	41	10.2	929	17
8	Illinois, United States	High_Yield	MG3	PI 593257	1.40	42	11.3	922	15
8	Illinois, United States	High_Yield	MG3	PI 548556	1.23	44	10.866666667	1004	17
8	Illinois, United States	High_Yield	MG3	PI 548362	1.30	42	11.65	929	16
10	Iowa, United States	High_Yield	MG3	PI 548522	1.31	45	10.6	929	19
10	Indiana, United States	High_Yield	MG3	PI 548585	1.23	42	10.5	921	16
10	Ohio, United States	High_Yield	MG3	PI 593463	1.34	43	8.8	929	18

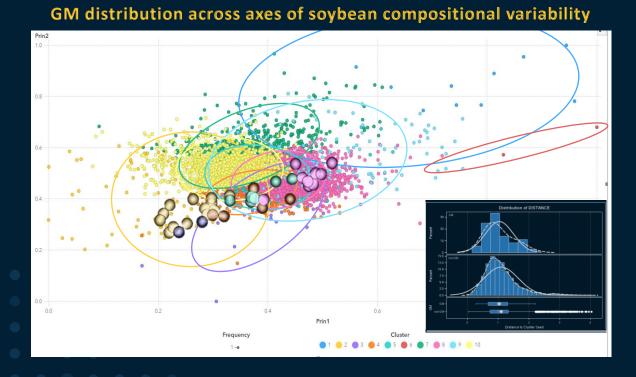
With human-inthe-loop

Take the decision



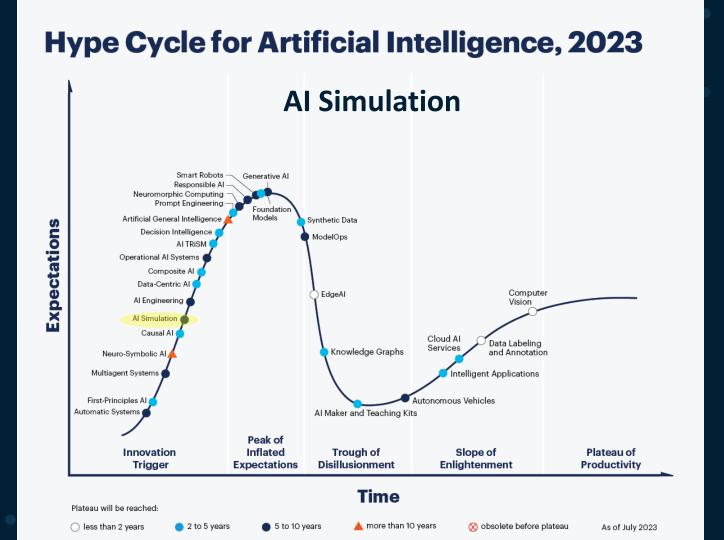


# Synthetic Data and Decision Intelligence Applied to Reference Varieties



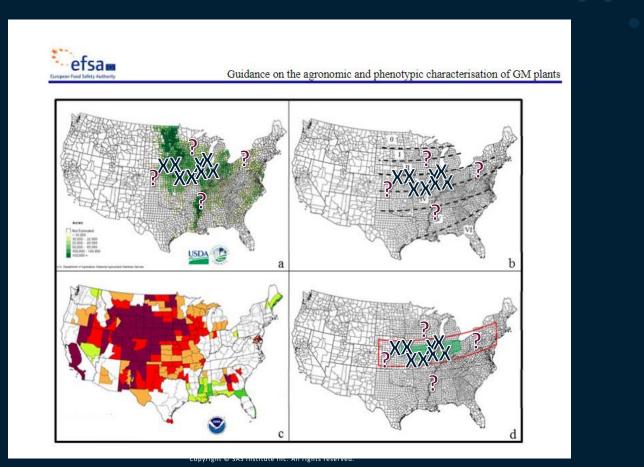
- Synthetic data is an enabler to create models where data is sparse or unknown
  - Imputation is one form of synthetic data
- Decision intelligence reduces intensive data sets into actionable classifications
- USDA Germplasm a useful source of reference information





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# **AI Simulation**







# **Data Simulation**

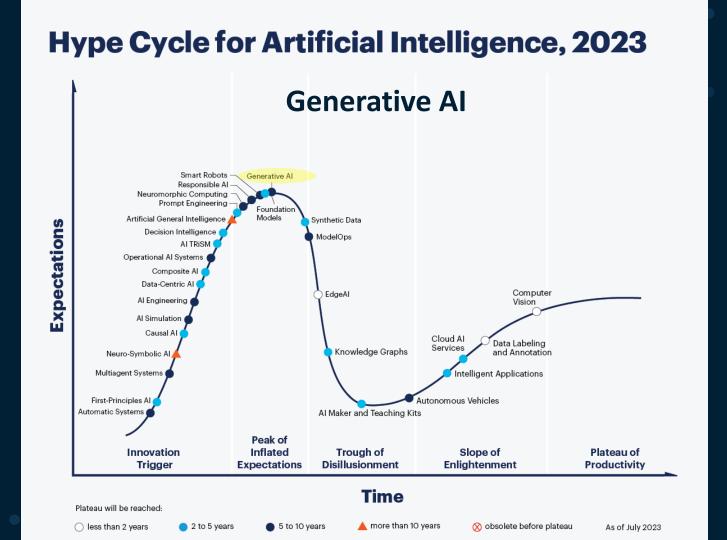
### Applied to Compositional Extrapolation

- Algorithms associated with statistics and machine learning can both provide estimates and predictions
- Partitioning into training and holdout data sets ensures generalizability
- Continuous covariate regressors provide a basis for extrapolation
- Anything can be modeled... do you have the data to do it?



Model to predict reference varieties in a sea of germplasm based on composition





<u>S</u>sas

### What is the best way to analyze GMO composition data to assess safety?:

Analyzing GMO (Genetically Modified Organism) composition data to assess safety typically involves a multi-faceted approach that combines various methods and considerations. Here's a general guideline for analyzing GMO composition data:

**Define the Safety Parameters:** Identify the specific safety parameters you want to assess, such as allergenicity, toxicity, and nutritional equivalence.

**Collect Comprehensive Data:** Gather data on the composition of the GMO and its non-GMO counterpart, including proteins, carbohydrates, fats, vitamins, minerals, and other relevant components.

**Statistical Analysis:** Use statistical analysis to compare the GMO and non-GMO data sets. Common statistical methods include t-tests, ANOVA, and multivariate analysis techniques to detect any significant differences.

**Evaluate Known Allergens and Toxins:** Assess whether the GMO contains known allergens or toxins and compare their levels to established safety thresholds.

**Use Bioinformatics:** Employ bioinformatics tools to analyze the DNA and protein sequences of the GMO for potential allergenicity or toxicity. Compare these sequences to established databases of known allergens and toxins.

#### Tell me more about statistics and machine learning for nutritional equivalence

Statistics and machine learning techniques play a vital role in assessing nutritional equivalence between genetically modified organisms (GMOs) and their non-GMO counterparts. Here's how they can be applied:

#### **Data Collection and Preprocessing:**

Collect data on the nutritional composition of GMOs and non-GMOs, including information on proteins, carbohydrates, fats, vitamins, minerals, and other relevant nutrients.

Preprocess the data by handling missing values, outliers, and normalizing variables to ensure that it's suitable for analysis.

#### **Descriptive Statistics:**

Start with basic descriptive statistics to summarize and visualize the data. This can include measures like mean, median, standard deviation, and histograms to understand the distribution of nutritional components.

#### **Hypothesis Testing:**

Use statistical hypothesis testing techniques to determine if there are significant differences in nutrient levels between GMOs and non-GMOs. For instance, you can perform t-tests or ANOVA to assess differences in means.

#### Machine Learning Classification:

Employ machine learning classification algorithms to predict whether a sample is GMO or non-GMO based on its nutritional composition. Feature selection and engineering are crucial in this step.

Common algorithms include logistic regression, decision trees, random forests, and support vector machines.

Tell me about a robust data analysis process to address EFSA GMO crop composition requirements for import registration. Apply the rules of European Commission Implementing Regulations 503/2013, EFSA Guidance for risk assessment of food and feed from genetically modified plants, EFSA Statistical consideration for the safety evaluation of GMOs, EFSA Guidance on the agronomic and phenotypic characterisation of genetically modified plants, and other relevant European sources. Apply additional well-suited statistical techniques to the problem to support a more rigorous safety evaluation within the data presented.

Addressing EFSA GMO crop composition requirements for import registration involves a systematic and robust data analysis process that complies with European Commission regulations and EFSA guidelines. Here's a step-by-step approach:

Step 1: Data Collection

1.1. Gather comprehensive data on the genetically modified (GM) crop and its non-GM counterpart(s), including information on genetic modifications, cultivation practices, and environmental conditions.

Step 2: Data Preprocessing

- 2.1. Clean the data to remove any outliers or errors.
- 2.2. Normalize or transform the data as necessary to ensure comparability.
- 2.3. Separate the data into appropriate categories or groups based on crop type, location, and other relevant factors.

Step 3: Statistical Analysis 3.1. Descriptive Statistics:

Calculate summary statistics (mean, median, standard deviation, etc.) for each compositional parameter in GM and non-GM crops. Visualize data using histograms, box plots, and scatter plots to identify trends and differences.



Also, describe an audacious and popular modeling technique that uses available data and would suitably test GMO compositional difference and equivalence.

An audacious and popular modeling technique that can be applied to test GMO compositional differences and equivalence is Machine Learning (ML), specifically Random Forest:

Data Preparation: Utilize the preprocessed data as input features and label GM and non-GM crops. Ensure the data is properly balanced and split into training and testing sets.

#### Random Forest Modeling:

Train a Random Forest classifier to distinguish between GM and non-GM crops based on their compositional data. Random Forest can handle high-dimensional data, capture complex interactions, and provide feature importance rankings. Feature Importance Analysis: Use the Random Forest model to identify which compositional parameters contribute the most to the classification decision. This helps pinpoint the most critical differences between GM and non-GM crops.

Validation and Interpretation:

Validate the model's performance using appropriate metrics (accuracy, precision, recall, etc.) on the testing dataset. Interpret the model's results to assess the significance and biological relevance of compositional differences. Equivalence Testing:

Integrate the model's predictions with equivalence testing techniques to determine if the observed differences are within acceptable limits.



# **Common AI excellence threads across organizations**

#### Metadata

- Common definitions •
- Data Dictionary ۰



#### **Data Ownership** ۲

Go-to-person

Usage guidelines



### Data trust

Consistency across sources Ease of validation

### Data Access

- Ease of use
- Tools



### **Reporting / Analytics**

- Single access point
- Growing need



### **Data Integration**

- Unfragmented data ٠
- Data ready for use ٠



### Architecture

- Standards
- Scalable solution(s) •



### Culture

- Break division silos
- Create transparency



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### **Data Regulation**

- Data provenance
- **Firewalls**



## How SAS supports 21<sup>st</sup> century regulatory science teams



#### ssess By-Site Refined Dif Transpose Error and... and Derive. Transpose Cluster Visualize Data observations Difference.. 2 EFSA Diff and Visualize Visualize Equiv Test Difference. Clusters 2 2 DiffTest **`**Diff and Visualize Difference. (cluster..

# Facile – for all study personnel

Traceable and integrated

Auditable from data to report

# **Overall Summary**

Trends in AI and Analytics

- Composite and First Principles AI enables better [statistical] inference
- Synthetic data and decision intelligence facilitate faster and more robust decision frameworks
- When done well, AI simulation supports extrapolation to 'edge scenarios'.
- Generative language models can summarize lots of information quickly and can spark ideation
- SAS enables regulatory scientists to adopt and expand multimodal analytics



# Questions

